Strategic Policy Forum on Digital Entrepreneurship


# Big data and B2B digital platforms: the next frontier for Europe's industry and enterprises

Recommendations of the Strategic Policy Forum on Digital Entrepreneurship

*April 2016*

A forum established by DG Internal Market, Industry, Entrepreneurship and SMEs

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# Foreword

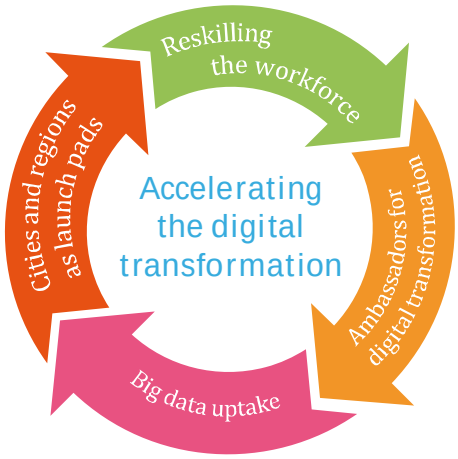
We Europeans already benefit in many different ways from the increasing amounts of data available today. Analysing large volumes of data (big data) is at the heart of things as diverse as medical research, weather forecasting and modern decision making. But it's also a resource that innovators harness to bring us more benefits as every day passes. Even greater rewards await us if we can learn how to tap these rich seams of big data.

For many years large manufacturers and indeed industry sectors have enjoyed efficiency gains by developing common platforms, for example common car platforms that form the base for a number of different models. Digital technologies create opportunities to extend the industrial platform concept to new levels – digital industrial platforms can be some or all of data exchanges, providers of common or standard functions, repositories of best practice and even marketplaces. They also change and re-shape value chains and like all such disruptions can create winners and losers.

In this report, one of four in the second series of reports from the Strategic Policy Forum, we set out our ideas to ensure Europeans make the most of the opportunities that big data provides and that Europe's industries and enterprises continue to play in the premier league when it comes to digital industrial platforms. I am grateful to my colleagues in the Forum, the many industry and other experts who provided their time and knowledge so freely, and finally the team at PwC who pulled it together so expertly and patiently. I hope readers find these positive and practical contributions useful and we welcome any feedback you have.

John Higgins

President of the Strategic Policy Forum
Director General DIGITALEUROPE




- Big data and B2B digital platforms: the next frontier for Europe's industry and enterprises

**Forthcoming blueprint**

- Cities and regions as launch pads for digital transformation

**Forthcoming report**

- Reskilling the workforce: digital skills for industry

**Forthcoming toolkit**

- Toolkit for decision makers to become ambassadors for digital transformation

# Big data and digital platforms

## Recommendations and transformational projects

### Six recommendations

1. Appoint Chief Data Officers (CDOs) in each Member State to take full advantage of big data based on non-personal or anonymised data; promote data quality and standards, champion effective data curation; and, maximise the social and economic value of public sector open data.
2. Invite the CDOs to work collaboratively and develop European guidance for enterprises on how to harness the benefit of big data in the public and private sectors, in the light of European values and sensibilities.
3. Develop an EU-wide action plan for the deployment of 5G that involves all stakeholders from industry, the public sector and funding providers, as well as explores innovative financing models.
4. Develop multi-vendor test beds for new generation digital solutions. These multi-stakeholder funded facilities would allow for the mutualisation of cyber-security, big data tests and third party assurance, thus facilitating the market uptake of these technologies by large corporates.
5. Promote European digital identity management solutions for objects and people.
6. Carry out a sector-by-sector analysis of the opportunities for the development of European business-to-business platforms. Establish multi-stakeholder groups in promising sectors to develop a sector action plan for such platform development.

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Executive summary

# The next frontier for Europe's industry and enterprises

Large data sets ("big data") and algorithms are valuable assets for economic growth and social progress. They are the new super power fuel of the economy of the future. From emails and videos to banking transactions, data sensors and CT scans, every day 2.5 quintillion bytes of data are created by everything from smartphones to satellites.[1]

A myriad of digital sensors in industrial equipment, vehicles and production systems worldwide contributes to an explosion of – mostly new – data. Each year, the amount of data being captured increases by a staggering 40 percent.[2]

### Algorithms and digital platforms take big data to the next level

Algorithms that perform calculations, data processing and automated reasoning are the new engines of companies, assisting them in analysis and decision-making.

Digital platforms allow the aggregation and sharing of data. By integrating their data through digital platforms, supply chain actors can increase the availability and accessibility of valuable information. This ultimately results in improved reliability, agility and effectiveness.

### Big data and the future of Europe

Big data and digital platforms will bring enormous benefits to European industry and enterprises. For example, industrial companies are expected to generate 3.6% per annum in cost reductions over the next five years by using big data in their daily business.[3]

In Europe, 71% of companies say that they expect to achieve advanced levels of digitalisation in 5 years. Yet today, only 28% of companies have managed to achieve advanced levels of digitalisation.[3]

Companies and governments need to take urgent action to accelerate the uptake of big data and digital platforms for the future competitiveness of Europe.

A

## Seizing opportunities

Big data presents enterprises with significant new opportunities. When properly processed, it can improve business performance by allowing enterprises to develop new business models, improve products and services, and bring about considerable economic and social benefits.

Big data is also a driver for innovation. By harnessing the power of big data and digital platforms, European industries can enhance productivity and performance, increase profitability, strengthen their competitive advantage, reduce risk, and pave the way for innovation.

### Using resources more efficiently

Using big data to manage resources more efficiently will also bring new growth and job opportunities. Better eco-design, waste prevention and reuse through behavioural and supply chain analysis could bring annual net savings for EU businesses of up to EUR 600 billion, while also reducing total annual greenhouse gas emissions.[4]

### Supporting decision making

Big data can get real results. Research from the Massachusetts Institute of Technology's Sloan School of Management found that large companies that adopted "data-driven decision making" achieved productivity gains that were 5 to 6 percent higher than other factors could explain.[5]

In order to fully benefit from big data, industries and enterprises have to design

### Digital opportunities

**100+** new digital platforms from non-tech companies expected in 2016[6]

Digital assets across the entire economy **doubled** over the past 15 years[7]

**81%** executives think that digital platforms will significantly disrupt industries[8]

### Era of autonomous vehicles

**>90%** of new vehicles sales will include telematics packages by 2020[9]

Partially and fully autonomous vehicles could reach **20%** of new vehicles sales by 2025[9]

### Redefining healthcare

The cost of developing a new drug reaches **EUR 707 million**[10]

**29 million** patients records compromised by security breaches between 2010 and 2013[11]

### Rise of smart industry

**3.8%** expected annual growth of the EU mechanical engineering sector over the next 10 years[12]

**3 million** people are employed in mechanical engineering in Europe[12]

to design and/or use data tools that help them to extract valuable information. Complex algorithms provide relevant insights by assessing data patterns and identifying correlations. Digital platforms are not only key for managing suppliers and connecting with customers. They also allow better communication and data sharing within and across the enterprise's borders.

### Responding to changing demand: toward mass-customisation

Demand for customised products and services is growing at a steady rate and is having an impact on every industry and every client relationship. Retail industries were amongst the first ones to implement customised products and services determined by big data analytics. The entertainment industry followed. Traditional manufacturing industries are also changing and shifting their modes of production. Car manufacturers, for example, are now capable of offering hundreds of options combinations for the same model.

### Creating competitive value chains

The adoption of digital technologies has most impact when it involves and integrates different actors and sub-activities throughout the value chain. By collecting and using data individually, different actors create silos or islands of information. This leads to inconsistent and redundant data at the value chain level.

Enterprises can make the most of big data by collaborating across the value chain. By establishing a data value chain, they can manage data holistically from capture to decision making, from the data generators to the data consumers.

By forming collaborative partnerships, different stakeholders can coordinate data collection across the value chain. The data analysis which can then be performed on the resulting data will enable the optimisation of service delivery and enhance the quality of the decision making process throughout the value chain.[13]

Digital platforms are approaching a total market value of

EUR 4 trillion[14]

### Taking the lead to stay ahead of the competition

With their transformative power, big data and digital platforms are changing the way value is distributed among existing actors and newcomers in the value chain. Big data is the goldmine of the 21st century and traditional industry players, as well as digital players are competing to keep control of the data generated by products and users.

B

## Overcoming challenges

The opportunities from big data and digital platforms are massive, especially in the three key sectors covered by this report: automotive, healthcare, and mechanical engineering. Yet, Europe needs to overcome a series of challenges to capture their full potential.

### A complex and fragmented regulatory environment

Big data and digital platforms require a clear and supportive regulatory environment. A paradigm shift in the EU regulatory environment is needed. Data collection, processing and exchange are no longer constrained by borders. Technical barriers to large-scale data creation and sharing are being overcome. So, patchworks of national regulations are at risk of becoming rapidly outdated, inappropriate or irrelevant.

The challenge for national governments and the EU is to review regulations linked to specific market problems.

For instance for autonomous cars, several EU directives concern vehicle safety and insurance liability. These have to be rapidly reviewed to enable the uptake of driverless cars. New harmonised regulations, such as the General Data Protection Regulation (GDPR) or the future medical devices regulations take into account big data, but companies need further guidance to implement them efficiently.

### Investment gaps in infrastructure

Large investments are required to upgrade Europe's physical, digital and security infrastructures to meet the demands of different industries. Europe needs to move to the next major phase of mobile telecommunications standards, increase wireless data speeds and extend network coverage.

This can be achieved by fixing Europe's investment gap in ICT and infrastructure. Massive investments are required in automotive to support the rise of connected vehicles and in healthcare to boost the widespread adoption of electronic health records (EHR).

Fast wireless networks are enablers for multiple industries including healthcare, automotive and manufacturing. Technologies such as fifth generation mobile networks and telecommunications standards (5G) will become the lifeblood of these major industries in less than five years.

Security infrastructure is also of critical importance. The widespread adoption of digital technologies together with the increase in the number of devices in networks now offer an even broader scope for hackers and espionage. It is vital to protect EU businesses from such risks, by providing an infrastructure to independently validate new security solutions.

### Lack of standards and interoperability

The interoperability of information technology systems is a precondition for the successful uptake of big data in Europe. The use of a common data format allows such interoperability. Up to now, no common rules or guidelines exist regarding the way data are stored, thereby impeding different systems to work together.

The challenge is therefore to develop and ensure the uptake of European standards allowing the extraction of necessary information across systems. As these standards are likely to be very specific, sector interoperability initiatives are required to agree on the terms, the methodologies for reaching a common language, and a common starting point.


### Deploying quickly and at large scale

Implementing big data and digital platform solutions requires significant managerial time, process transformations, new IT tools, new skills and financial investments by companies. Implementation affects all internal services and all business processes from the supplier to the client.

Driving business with real-time data represents a major transformation for product and service companies, and a big shift from traditional models based on delayed and partial reporting. Market forces will push companies in all industries to adopt these new technologies. Those who resist the change or do not understand its value will lag behind and disappear.

Dealing with the rapid deployment of big data and digital platforms is fundamental for the competitiveness of the EU economy. A strong demand of ICT and a strong local supply go hand in hand. The main way to strengthen the demand side is by giving companies the confidence to use big data, ensuring that standards are developed, investing in cybersecurity, and providing clear guidelines for the implementation of regulations. The supply side also needs to be strengthened, by building competencies, industry centres of excellence, platform collaborations, and by getting the actors to come together.

C

## Recommendations

Based on the results of an extensive desk research and interviews with key industry players, the Strategic Policy Forum on Digital Entrepreneurship has developed a set of industry and issue-specific recommendations.

The recommendations were drafted on the basis of four principles (see box 1) which the forum believes are key to create a favourable environment that will allow European companies to fully benefit from the digital transformation and confirm their leading position in the modern digital economy.

Harnessing the power of big data and digital platforms at EU level is crucial for all industry players, old and new, to increase their competitiveness. The following recommendations are essential for ensuring Europe's digital future.

**Box 1: Four principles for the recommendations**

- Large data sets ("big data") are valuable assets for economic growth and social progress
- European industry and enterprises can grow and create jobs faster through better use of big data and digital platforms
- Digital technologies can deliver additional benefit when used in collaboration across the value chain
- European leadership in business-to-business platforms will support European economic growth and job creation

1

### Appoint Chief Data Officers (CDOs) in each Member State to take full advantage of big data based on non-personal or anonymised data; promote data quality and standards, champion effective data curation; and, maximise the social and economic value of public sector open data.

Big data is a largely unknown and untapped source of benefits for the European economy and social progress. Yet, there is currently more focus on its risks rather than its benefits. Given the transversal impact of big data, a new organisation at government level is required to address big data opportunities or changes in all policies.

Appointing a Chief Data Officer per Member State would facilitate the development of a common strategy to drive big data, the implementation of new and required standards in Europe, and the sharing of best practices to maximise the outcomes of big data across domains, sectors, competencies and geographies.

2

## Invite the CDOs to work collaboratively and develop European guidance for enterprises on how to harness the benefit of big data in the public and private sectors, in the light of European values and sensibilities.

The transition from a patchwork of 28 different laws and heterogeneous sets of rules on data protection across EU countries to a common new General Data Protection Regulation (GDPR) is a major step. It simplifies the regulatory environment and thus eliminates unnecessary costs and reduces the administrative burden for EU companies. However, implementing this new framework, in conjunction with other constraints at company level, will be complex and challenging.

Guidelines and guidance are necessary and valuable to avoid misunderstandings and misinterpretations. Without clear guidelines, EU companies will face challenges to use data as a business driver and expose themselves to risks and additional costs.

An independent advisory panel made up of national chief data officers assisted by industry experts could forge consensus on detailed guidelines for capturing the full benefits of data-driven innovation in Europe, guaranteeing similar and fair market conditions for all market players while protecting consumers, workers and business investments.

3

## Develop an EU-wide action plan for the deployment of 5G that involves all stakeholders from industry, the public sector and funding providers, as well as explores innovative financing models.

Fast wireless networks underpin and enable digital growth in all industries including healthcare, automotive, and manufacturing. Yet, the EU is lagging behind in the adoption and implementation of fifth generation mobile networks and telecommunications standards (5G).

This issue has been widely recognised and 5G is the subject of multiple ongoing initiatives at the public and private levels, including the 5G Infrastructure Public Private Partnership (5G-PPP) EU flagship initiative.

There is a need to push this matter further and to develop a coordinated and EU-wide action plan with the involvement of all stakeholders (industry, public sector, funders, and EU representatives) for 5G deployment. New innovative financing models should also be explored to ensure a full-scale development.

4

## Develop multi-vendor test beds for new generation digital solutions. These multi-stakeholder funded facilities would allow for the mutualisation of cyber-security, big data tests and third party assurance, thus facilitating the market uptake of these technologies by large corporates.

New digital solutions raise the cost and complexity of tests, validations and certifications for potential clients. Internet of Things (IoT) devices and network architectures raise new security concerns. Digital innovations, such as connected vehicles and autonomous driving, together with the increase of devices in networks, now offer an even broader scope for hackers and espionage. Security is becoming a real concern for automotive and mechanical engineering, as these sectors are highly sensitive to cyber-attacks.

The validation of new generation solutions requires neutral and independent validation mechanisms with the capacity to rapidly perform complex tests and issue third party assurance for future clients, from comfort letters to certification.

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5

## Promote European digital identity management solutions for objects and people.

Digitalisation fundamentally multiplies the notion of digital identity of a person through different applications from the public and private sectors.

New kinds of objects, mobile phones, PCs, vehicles, files, applications or processes are lacking a unique, traceable and manageable system of digital identities. Yet, digital identity is an enabler of trust and, as such, a key component of the Digital Single Market (DSM).

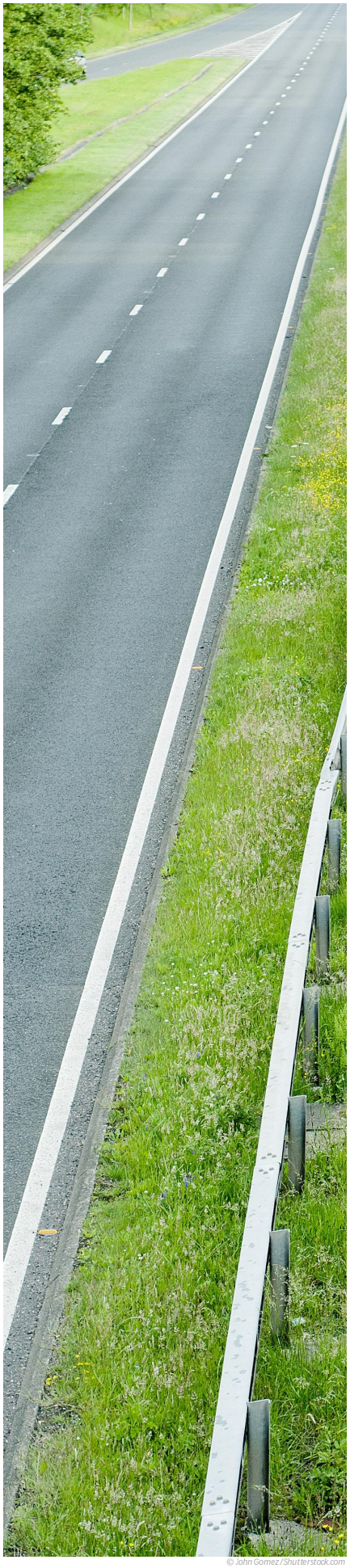
This new digital ID paradigm requires a high-level of cross border interoperability and new management solutions.

A digital identity system, interoperable at EU-level, would comprise all information that uniquely describes an entity, a person or a device. This legal digital ID (E-ID) would include similar properties as ID cards and serve the purpose of identity verification and data, person and object authentication.

6

## Carry out a sector-by-sector analysis of the opportunities for the development of European business-to-business platforms. Establish multi-stakeholder groups in promising sectors to develop a sector action plan for such platform development.

It is estimated that digital platforms will capture 30 to 40% of the value in industrial chains.[15] They will be the engine of tomorrow's growth, industrial transformation and job creation. Though Europe is a leading ICT player, in many industries, European digital platforms are not developed enough to be leaders and have not yet established an international presence. Boosting the growth of EU digital platforms is a matter of urgency for the future competitiveness of Europe's industries and enterprises.



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D

# From recommendations to actions: 3 transformational pan-European initiatives

Given the magnitude, strategic importance, urgency, and complexity involved in the implementation of our recommendations, we propose to launch three pan-European transformational projects that will serve as a backbone for testing, fine-tuning and implementation. The three projects will:

- Prove the economic and social value of big data;
- Accelerate European leadership in business-to-business platforms;
- Improve value-generating collaboration across value chains.

## 1

### Make Europe the first market for autonomous vehicles

Objectives: accelerate the creation of a true pan-European level playing field – encompassing operational, regulatory, infrastructure and data dimensions – for private companies to test and implement their solutions around autonomous vehicles; and make Europe the leading world market for autonomous vehicles, reinforcing and developing European industry leaders.

How: create a coalition or public-private partnerships (PPP) for European autonomous vehicles, made of committed Member States and industries. Their purpose is to achieve geographical scope for a common implementation framework including regulation, standards, data exchanges, security and safety services. Financed for three years by the Juncker plan, as well as by the industry, driven by a steering committee and an operational task force and using rapid prototyping and testing, this project will foster cross-country collaborations across the autonomous vehicles value chain by 2020.

Next steps: mobilise and regroup the key leaders of the GEAR 2030 initiative, C-ITS platform and other pan-European and national initiatives on autonomous vehicles in a working group to define the scope and the feasibility of this bold pan-European project.

## 2

### Put big data at the heart of a project to improve health outcomes and reduce care costs associated with a major disease

Objectives: for a specific, carefully selected disease, show how big data can bring benefits at all levels of the value chain by easing the process of drug discovery, improving the quality of diagnostics, enhancing drug effectiveness, ensuring patient's safety and reducing R&D and healthcare costs.

How: collaboration with representatives from patients organisations, governments and pharmaceutical and med-tech companies (public private partnership), build a pan-European, high-quality, patients data repository by using the latest technologies and big data breakthroughs.

Next steps: gather a group of big data and medical experts to establish the terms of reference for this cross-value chain pan-European project.

## 3

### Create a pan-European smart industry programme

Objectives: accelerate the digitalisation of European factories through the uptake of new automated technologies and big data to provide a new competitive advantage for EU industry.

How: create a pan-European incentive programme led by industry to foster investment in digital plant equipment, digital platforms and skills to save energy and resources, as well as to improve working conditions and plant performance.

Next steps: gather the leaders of national "Industry 4.0" and "Industry of the future" initiatives as well as industry associations' and social partners leaders to define the specifications of the incentive programme.

Background

# Seizing the opportunities of the digital revolution

1

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A

## Big data and digital platforms

### Big data

Big data has no single internationally recognised definition. Most definition are based on the three 'V's[16]:

- Volume (a reference to data stores of petabytes or above);
- Velocity (the requirement for real-time collection/analysis of data); and
- Variety (generation of data in diverse formats from a variety of collection mechanisms).

The report will use the definition used in the EU Data protection reform and big data Factsheet of March 2016.[17] Big data is defined as large amounts of different types of data produced from various types of sources, such as people, machines or sensors. This data could be climate information, satellite imagery, digital pictures and videos, transition records or GPS signals.

### Big data analytics

Big data analytics is complementary to big data, as it is the process of examining the data sets through algorithms. It is defined as the use of mathematics and statistics to drive meaning from data in order to make better decisions.

There are three kinds of analytics:

- descriptive analytics tell what happened in the past, but not why it happened or how it might change;
- predictive analytics use the past data to model future outcomes;
- prescriptive analytics advise on the best outcomes, considering several scenarios.

### Digital platforms

Digital platforms provide the technological basis for delivering or aggregating services/content and mediate between service/content providers and end-users.

They integrate the components of industrial value chains in a seamless communication between interoperable business processes (e.g. design, production, sales, logistics, and maintenance).

B

## The digital platform age

Digital platforms are more than simply developing and deploying digital tools. According to the Massachusetts Institute of Technology, in 2013, 14 of the top 30 global brands by market capitalisation were platform-oriented companies.[18]

### The rise of digital platforms redesigns companies' digital strategies

According to IDC, there will be more than 100 new digital industry platforms from non-tech companies as early as 2016.[6] Digital platforms will significantly disrupt industries: 4 out of 5 executives surveyed by Accenture believe that in the future, industry boundaries will dramatically blur, as platforms reshape industries into interconnected ecosystems.[8]

To build platforms, companies must use their industry knowledge and experience to be able to innovate, develop and deploy products and solutions rapidly and efficiently. Only then, they will be able to drive their digital strategies.

While many businesses are using digital initiatives to harness social, mobile, analytics, and cloud technologies to gain competitive advantage, far-sighted leaders are bringing together their digital initiatives under umbrella platforms. Building umbrella platforms will bring in better ways of operating, as well as create new revenue streams.

### Competing for data management

Industry players in the automotive, healthcare and pharmaceutical industries need digital platform providers to be able to use data and stay competitive. However, these players are competing to keep control of the value chain, and to control the data produced by products and services users.

Digital players are now increasingly present across the value chain. As an example, in the automotive industry, digital players already manage "driver data", produced by people using services offered in connected vehicles. These include entertainment and social media data, health data, insurance and home integration data. Vehicles manufacturers and digital players are collaborating to use context data and offer new services. They are competing for the management of this data.

### Algorithm economy

Complex algorithms lie at the heart of big data analytics by creating the necessary information streams through correlation and prediction models. In this sense, they are essential tools in order to structure, develop and interpret aggregated data.

As such, algorithms are truly transformative and can generate innovation and business values. Dynamic algorithms are the core of new customer interactions and have an enormous potential of value creation across sectors and industries. For instance, algorithms can define the right mix and dosage of drugs for a patient, or the driving conditions of autonomous vehicles.

Consequently, people will increasingly act based on algorithms' recommendations, which will define new products and services. For this reason, algorithms will generate a significant part of external trade and will heavily influence economies worldwide. This is the promise of the algorithm economy.

Algorithms are the DNA of software and their predominance will only increase in the digital age, especially with the growth of the Internet of Things.

## Value creation through digital platforms

Digital platforms have already become an indispensable tool for the use of data. Digital platform providers are playing an increasingly central role in the value chain and in value generation. Going forward, all EU industries will have to focus on value creation through digital platforms.

For example, in the healthcare, industry data and sensors allow the rise of new innovative business models, which are re-designing health management. The pharmaceuticals value chain is being heavily reshuffled to allow for personalised monitoring and performance-based drug production.

## Investing in digital tools to boost performance

### *Recognising the power of digital tools at C-level*

According to the 18th Annual Global CEO Survey by PwC[19], CEOs from the healthcare, automotive and mechanical engineering industries are highly aware of the importance of data and data analytics to create value for their companies. 60% of healthcare CEOs rate data and data analytics as having "very high value" for their organisations, compared to 45% of all CEOs. Overall, 90% of automotive CEOs and 89% of healthcare CEOs identify data and data analytics as having quite high or very high value for their organisations.

### *Healthcare CEOs are aware of the disruptive power of digital technologies*

Healthcare CEOs are slightly positive about the economy and confident of boosting revenues. They are focusing on using technology to create value in new ways, developing diverse and dynamic partnerships and cutting costs.

According to the PwC Digital IQ Survey 2015[20], mobile technologies to engage with customers, cyber security and data mining, as well as analysis tools are at the top of the list of digital technologies that healthcare CEOs deem strategically significant. They also see more potential in robotics and wearable devices than CEOs in many other sectors. However, 60% are apprehensive about the speed at which technology is evolving. 71% of them are anxious about cybersecurity – a must-have where confidential health records are involved.

The exploitation of Big data through data mining and analysis and cybersecurity are the two technologies with most impact according to the healthcare CEOs. On top of Big data and cybersecurity, operational efficiency can generate most value.

### *Automotive CEOs are worried about disruptions of the value chain*

Automotive CEOs place particular weight on data mining and analysis, mobile technologies for engaging with customers and tools for boosting cybersecurity. They are increasingly anxious about the pace of technological change: 55% now worry about keeping abreast of new technologies, compared to 49% last year.

Automotive CEOs recognise the value digital technologies can deliver. They say the main benefits include making better use of the data they collect, achieving operational improvements and enhancing the customer experience.

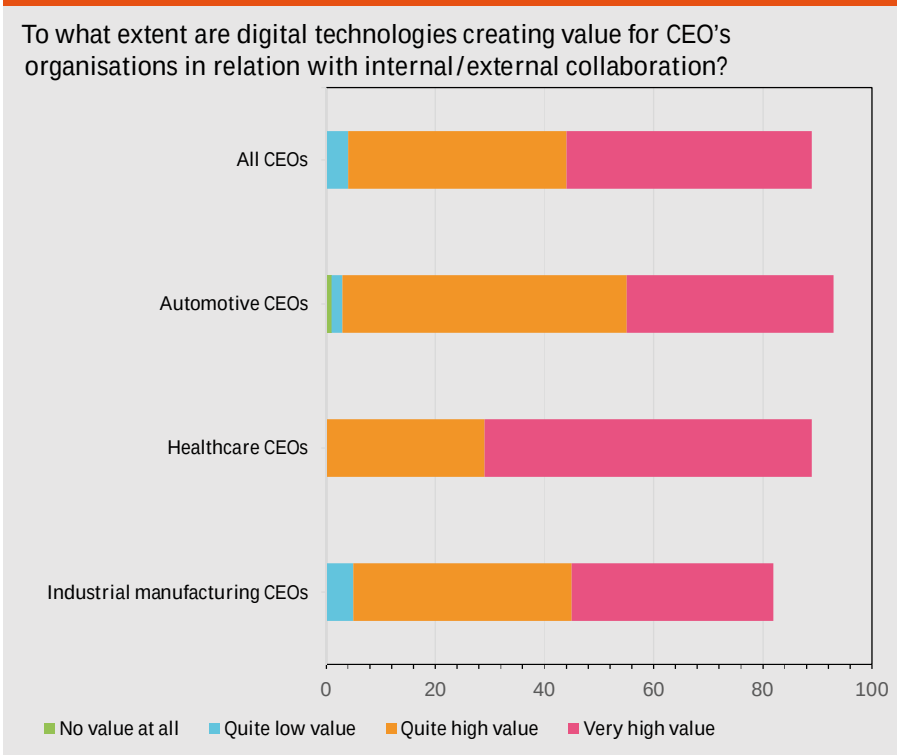
However, a clear vision of how digital technologies can achieve competitive advantage is essential to maximise the return on investment, as is a CEO who personally champions the use of digital technologies and a solid plan for implementation.

### *Mechanical engineering CEOs are capitalising on the digital revolution*

Mechanical engineering CEOs are less concerned about technology companies breaking into their own industry – and less interested in entering the technology sector – than other CEOs. Nevertheless, they are actively capitalising on the digital revolution.

They consider mobile technologies for engaging with customers (73%), cybersecurity (72%), as well as data mining and analysis (70%) as particularly important. They also stress the importance of robotics and 3D printing. However, they are increasingly worried about the speed at which technology is changing (54%, up from 43% last year). The growing number of cyber threats is another major source of concern.

**Figure 1: Healthcare CEOs report on the power of digital transformation**




*Source: PwC's 18th Annual Global CEO Survey[19]*

# Autonomous driving: a big opportunity for European industry

3

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A

## Taking the fast lane towards digital opportunities

Connected vehicles, e-commerce, autonomous driving and industrial Internet have emerged as major driving factors of automotive digitalisation. With a global economic potential of EUR 120 billion revenue p.a. in connected vehicles equipment – hard- and software[11], the digitalisation of the automotive industry is set to radically transform our transport and mobility patterns.

### Connected and autonomous vehicles: driving the push for digitalisation

The connected vehicle market for passenger vehicles is undergoing exactly the kind of growth that creates jobs and advances technology developments in the sector. As illustrated in Figure 2, the connected vehicle market is expected to grow significantly in the coming years. By 2020, over 90% of new vehicle sales will include telematics packages.[9] European OEMs and Tier 1 suppliers are now heavily investing in the second wave of mobile services. They have understood that these trends may in turn be impacting their market position in the long-run. New market players do not want to be left behind and are now entering the industry. Providers of telematics, content, technology and Big data, telecommunication companies and insurers are taking a cue from market leaders and strive to get their share of the digitalisation opportunity.

### Big data and digital platforms: arenas of innovation, competition and growth

Both connected and autonomous vehicles, make the automotive sector one of the largest data generators. Hence, rapidly increasing requirements for data management are driving investments in big data and digital platforms. By revealing patterns between different data sources and sets, big data applications allow OEMs to learn from consumer and vehicle data insights. In addition, transport infrastructure, social networks, blogs, online services or experts also serve as external data sources.

More important to OEMs, Big data enables the customisation of in-vehicle communication with drivers (e.g. in terms of navigation or aftersales services). It allows for unprecedentedly customised driver-provider interactions and shifts the innovation focus from products to consumers and data evaluation.

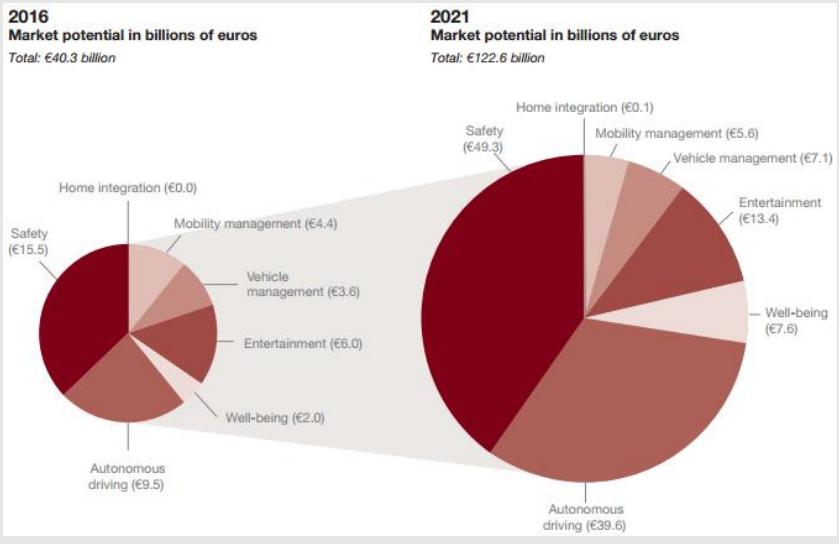
Data is evolving as a vital production factor. big data and digital platforms further enable vehicle makers to fully become mobility service providers. Overall, consumer aggregation is turning into the sweet-spot of automotive mobility services similar to consumer electronics.

### Autonomous driving: the next frontier

From connected vehicles to self-driving vehicles, driverless vehicles are set to become the game changer of the coming years. Autonomous vehicles move without human intervention. They use artificial intelligence, sensors and satellite navigation systems and therefore transfer several hundred megabytes per second communicating with external platforms and back-ends. These technological advancements come with new technical requirements. New IT systems, better data management services, enhanced security and compliance mechanisms are only a few of these new requirements.

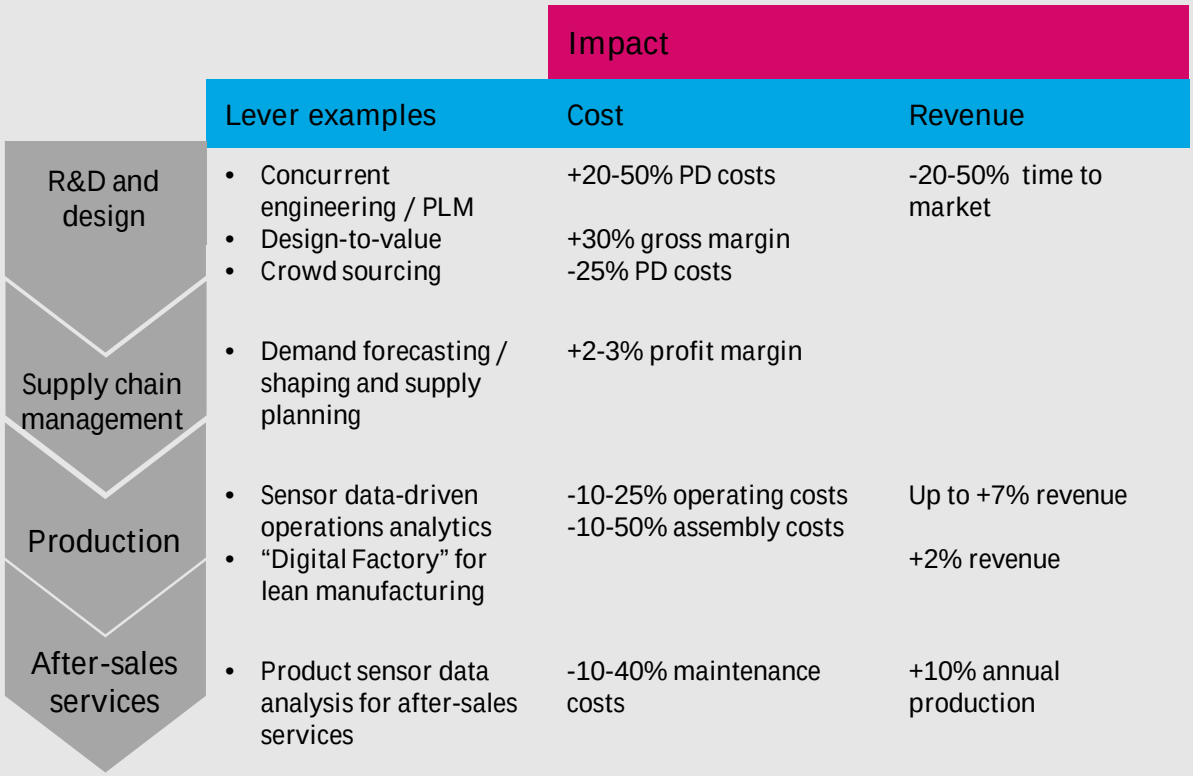
Partially and fully autonomous vehicles could reach 20% of new vehicle sales in 2025. Autonomous driving opens the door to new mobility services and ownership models exceeding established vehicle sharing concepts. Transforming the vehicle into an extension of our home and workplace, services for in-vehicle experience will provide an estimated EUR 3,300 revenue per household and year.[9]

Figure 2: Development – Total market connected vehicles 2016-2021




*Note: Totals may not reflect sums due to rounding. Passenger vehicles only, excluding light commercial vehicles.*
*Source: Strategy&, 2015[9]*

Figure 3: Value creation with big data




*Source: McKinsey*[21]

B

# Creating a clear and supportive European regulatory framework for the autonomous vehicle era

## Rapid technological advances and regulations aren't mutually exclusive

Europe is home to some of the largest auto manufacturers across the globe. It is no secret that these major automakers and tech companies are now racing to develop, test and sell fully autonomous vehicles. However, the future prosperity of the European automotive industry does not simply boil down to the number of auto manufacturers working on prototypes for self-driving vehicles.

It has to be acknowledged that, without a clear and supportive European regulatory framework for connected and automated driving, the uptake of the self-driving market will simply not happen in Europe.

## Thinking one step ahead of a heterogeneous legal framework hindering the uptake f autonomous vehicles

According to a preliminary review in the UK, in 2015, autonomous driving impacts a very large number of directives and regulations that have to be reviewed and aligned to foster its development:

The 1968 Vienna convention, Directive 2003/59/EC on training and initial qualifications of professional drivers- Directive 2006/126/EC on driving licence (DG MOVE) - Directive 2009/103/EC ('Motor Insurance Directive' -DG FISMA) and national rules - Product Liability Directive 85/374/EEC (DG GROW) - Directive 2007/46/EC on vehicle approval (DG GROW) - Roadworthiness Directive 2014/45 (DG MOVE) and national legislation - ITS directive 2010/40/EU (DG MOVE) and national law - Directive 95/46/EC on data protection, and national rules (DG JUST), Directive 2002/58/EC on privacy in electronic communications (DG CNECT) Directive 2007/46/EC on vehicle approval and UN regulation 116 on anti –theft devices (DG GROW) - Directive 2008/96/EC on infrastructure safety management.

## The high complexity of the regulatory framework for connected and autonomous vehicle lies in its heterogeneity

The regulatory agenda requires a special priority and effort by all stakeholders to coordinate and plan regulatory changes in a favourable timeframe for the industry and to the benefit of users.

In that vein, forward-looking countries such as Sweden, Netherlands, United Kingdom, Germany and Spain did not wait for a European regulatory framework and have already greenlighted road tests. Other European countries are also currently drafting new legislations and safety regulations providing greater flexibility to road use of semi-autonomous vehicles. Efforts are also placed in pushing for amendments to the Vienna Convention. For instance, Belgium and Sweden have already proposed to include autonomous vehicle systems within the scope of the definition of driver.

## Hitting new heights for a comprehensive European regulatory framework for connected and automated driving

Outward-looking European countries are already thoughtfully producing proper regulations for connected and automated driving, so how about creating a European framework altogether?

Regulating at the European level entails the development of a reliable, resilient and comprehensive regulatory framework capable of strengthening the competitiveness of the European economy in such a dynamic and innovative field as the automotive industry. It requires taking the time to consult all interested parties rather than falling into the trap of over-reaction leading, to an oversimplified or too restrictive regulatory framework.

The case of the eCall solution shows the positive link between a mandatory regulation and the speed of the adoption of the connected vehicles. The European eCall solution, an integrated telecommunication solution helping in case of serious accidents, was supposed to be implemented in all new vehicles as from October 2015. However, European regulators authorised OEMs to push back the implementation of the eCall solution by three years and the decision led to a decrease in the adoption speed of the connected vehicles.

## Making the most of two scenarios for the uptake of connected and automated driving

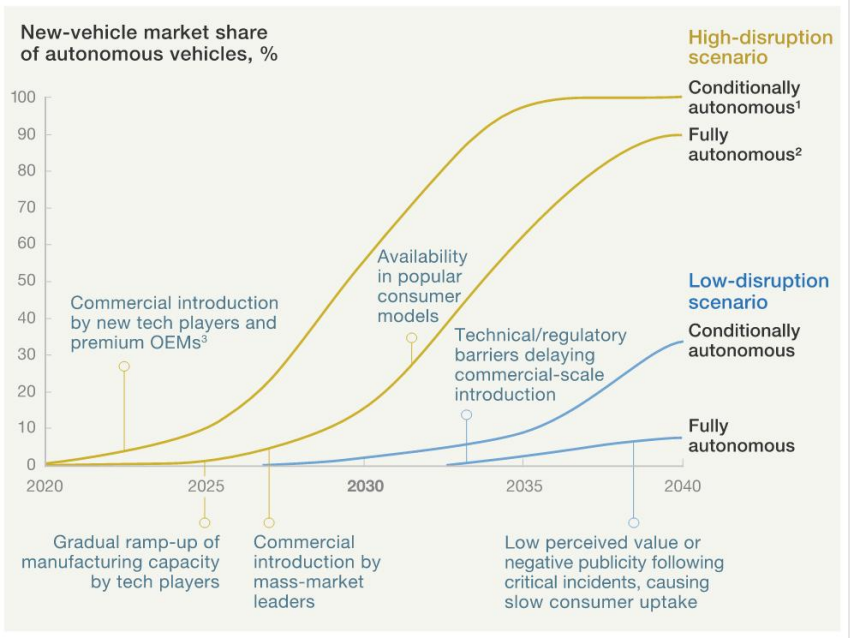
With growing competition from the US and Asia, the stakes related to the development of a European regulatory framework for self-driving vehicles are simply too high to be dismissed.

The speed and scope of potential future regulations open up the possibility for two most likely scenarios: a low-disruption scenario and a high-disruption scenario (Figure 4).

The former considers that current sales growth and regulations will remain on the same track, while the latter anticipates revised safety regulations and enthusiasm on the consumer side.

While Europe greatest risks lie in the regulatory patchwork, the US's biggest threat lies in its ageing infrastructures. Overall, Asian companies could benefit from the high connectivity of its countries and from their higher regulatory agility.

Figure 4: Scenarios for the penetration of autonomous vehicles




| Factors in disruption scenarios | High disruption | Low disruption |
|---|---|---|
| Regulatory challenges | Fast | Gradual |
| Safe, reliable technical solutions | Comprehensive | Incomplete |
| Consumer acceptance, willingness to pay | Enthusiastic | Limited |

[1]Conditionally autonomous car: the driver may take occasional control.
[2]Fully autonomous car: the vehicle is in full control.
[3]Original-equipment manufacturers.

Source: McKinsey[2]

## Working towards the creation of a European regulatory framework for connected and automated driving

The Commission has set up a high-level group on largely automated vehicles. This group gathers the relevant Commissioners, Ministers and stakeholders (CEO level). The group first met on 26 January 2016 and is established for two years. It will develop a roadmap on highly automated and connected vehicles, including a review of the EU legislative and policy framework, the EU financing tools that could foster the uptake of such vehicles as well as of the competitiveness aspects for the EU industry.

### Moving forward

- ✓ ❶ Develop a common strategy to coordinate and plan regulatory changes in all member states
- ✓ ❷ Build momentum for the creation of a European regulatory framework for connected and automated driving

C

# Fixing the ICT and infrastructure investment gap

## Overcoming the lack of investment in ICT in Europe

In a competitive environment, European automotive companies are waking up to the fact that they can no longer take their leading position in R&D investments for granted. Investments in the ICT sector is trailing compared to the US (with only 1/6 of US investment ).[23] The 2015 Single Market Integration and Competitiveness in the EU and its Member States report indicates that Europe has a significant ICT investment gap with accumulated levels in Europe corresponding to one third of those in the US.[24]

### ICT will bring tomorrow's growth

30 to 40% of the value in the automotive value chain is expected to be captured by digital providers.[15] European companies may be investing in projects related to ICT and digital platforms but they still have to collaborate with digital players such as Microsoft and Google (respectively 4th and 6th top R&D spenders in 2015).[25] Big digital players are using their leading position to make the most of every opportunity that comes along the value chain of the automotive industry.

### Stepping up investments in multi-vendor test beds

The development of multi-vendor test beds is a necessity to mutualise the costs of tests, validation and certification of the new generation of digital automotive applications and then facilitate the uptake of the most performing ones in a trusted framework. These validation settings for innovative solutions are well suited to disrupt traditional market channels, transform business processes and organisations, as well as take the customer experience to another level. They allow SMEs to test their solutions in live test-beds, which speeds up the adoption of a new generation of solutions. Building the right financing model with public-private partnerships to invest in infrastructures is the first step to maximise the impact of multi-brand test beds.

**Moving forward**

- ✓ ❹ Secure a higher level of investments in ICT and multi-vendor test beds

D

## Paving the road to a secure and connected operational framework

### Enhancing security and IOT digital management solution

Trustworthy storage solutions and cybersecurity are key to ensure the consumer's acceptance and safety for connected vehicles.

The increase of IoT in the automotive industry wire presents a massive security risk, while security solutions are only catching up with the last generation of cyber threats. The security in IoT represents an unprecedented challenge and requires massive investments.

### Improving the penetration of the next generation mobile networks and the level of road infrastructure investments

Most of Europe's 78.2% of mobile broadband penetration focuses on 3G networks. The limited coverage of the next generation mobile connections presents a barrier to implementing use cases for autonomous driving highly depending on real-time data. The European standard for vehicle-to-x communication established in 2014 cannot speed up implementation if only small amounts of data are transferred in 3G networks.

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With 63%, the European 4G network coverage seems high. However, in comparison to 97% of coverage in North America or 100% in South Korea, it is clear that a higher level of coverage is needed in Europe.[26] Moreover, only 53% of Europeans will have migrated to 4G networks by 2020, which will further slowdown the implementation of connected innovations. [27]

### Accelerating the deployment of 5G networks along highways

The vehicle of the future will be part of a connected world where superfast digital networks give access to communication, higher safety, improved environmental standards, entertainment, knowledge and personal contacts, to anyone, anywhere and at any time.

Connected vehicles will require even more bandwidth than what is currently provided by 4G and 5G. The deployment of faster and higher bandwidth is therefore a must for autonomous vehicles.

Investment in physical and digital technologies are far beyond telecom networks. Roads have to be equipped with new generation sensors and systems to enable a full operating model and supervision of highways. Development and implementation of big data technologies is a key enabler.

Europe should secure its competitive advantage by taking early steps to facilitate 5G mobile infrastructures to ensure the creation of high-speed wireless networks for vehicles' cloud based services (e.g. in the form of hot spots and road investments enabling automated driving).

**Moving forward**

- ✓ ❸ Step up efforts to achieve 4G and 5G connectivity on highways in order to secure the continuity of coverage
- ✓ ❺ Support the development of an effective system of digital identity to allow secure testing of connected and automated vehicles

**2.3 million** high-skilled jobs in automotive manufacturing

= 7.6% of the EU's manufacturing employment[28]

E

# Fostering standards and interoperability

## Standards as a prerequisite for EU competitiveness

The introduction of digital platforms in the automotive industry requires the active collaboration of different actors of the automotive value chain. The same standards are needed in the automotive industry, from Tier 3 suppliers to vehicle manufacturers.

Some large players can be tempted to develop their own "closed standard", but this independent approach generates a closed ecosystem and locks in customers within the system. Closed standards de facto exclude smaller players and impede the development of the market.

Open or multi-players standards are therefore necessary to enable a single market and to avoid the development of multiple standalone markets, with their proprietary system.

## Moving forward with the European Commission support to standards

The Platform for the Deployment of Cooperative Intelligent Transport Systems in the European Union (C-ITS Platform) was created by the European Commission services (DG MOVE) in November 2014 with the clear intention to support the emergence of a common vision among all actors involved in the value chain. Its aim is to analyse and determine where investments should start, how to stimulate the emergence of business cases, how to foster interoperability and how to pursue cooperation between public and private stakeholders.

The C-ITS Platform represents all of the key stakeholders along the value chain including public authorities, vehicle manufacturers, suppliers, service providers, telecom companies etc.

In January 2016, the European Commission also launched the High Level Group for the automotive industry "GEAR 2030" in order to boost competitiveness and growth in the automotive sector. The High Level Group started to work on the following key priorities to tackle the challenges affecting the competitiveness of the European automotive industry:

- the adaptation of the value chain to new global challenges,
- the automated and connected vehicles,
- trade, international harmonisation and global competitiveness.

GEAR 2030 has already put a special emphasis on the creation of an ambitious and forward-looking regulatory framework for automated and connected vehicles which should enable Europe to become an absolute leader again in terms of standards.

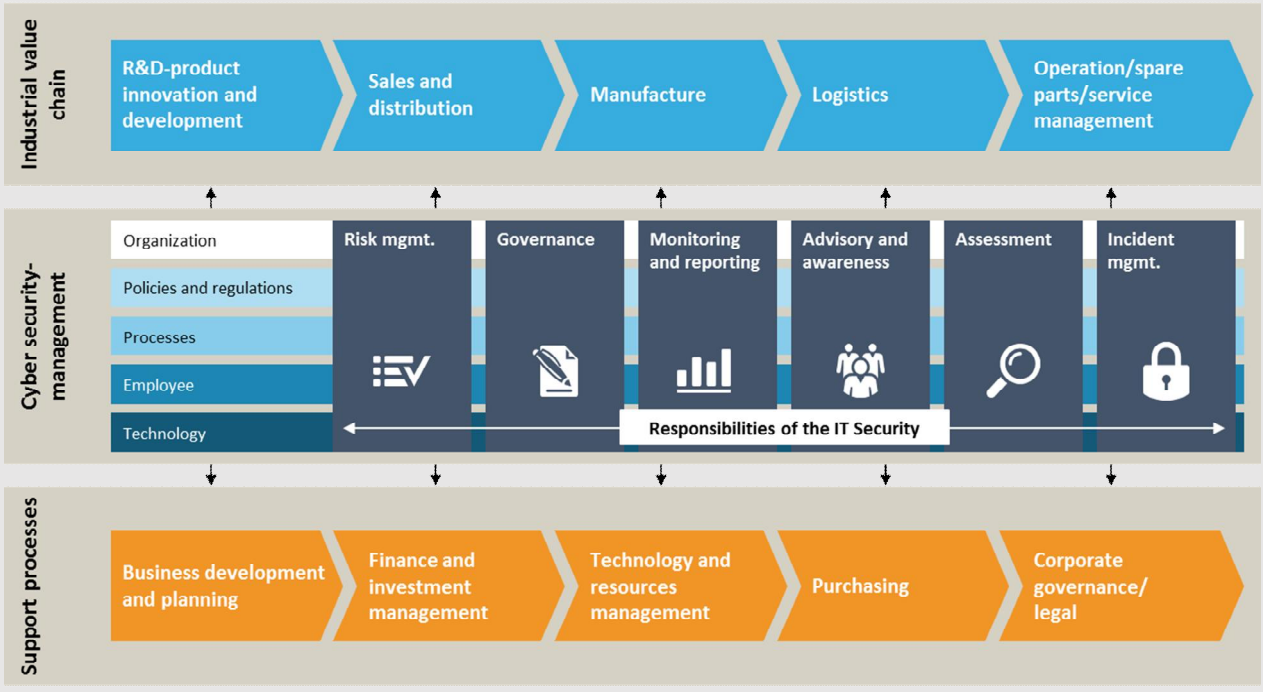
## Conveying a sense of urgency for the implementation of standards

Standards dedicated to vehicle-to-vehicle (V2V) communications and to intelligent transport systems have already been created. However, new generations of open or multi-players standards for autonomous vehicle are still required to enable the uptake of the industry. The global industry should therefore speed up its efforts to create, accept and implement these standards.

### Moving forward

- ✓ ❶ Support the development of standards for connected and automated driving to ensure the interoperability of data systems
- ✓ ❷ Create detailed guidelines to help firms to implement new norms and standards successfully

Figure 5: Cyber security management needs to impact all divisions and should include partners, suppliers and services




Source: PwC Analysis

F

# Establishing successful European platforms

## Europe is lagging behind for digital platforms

Digital platforms are expected to capture between 30% and 40% of the automotive value chains.[15] Several kinds of platforms are growing rapidly:

- Connected vehicle platforms;
- Community – e-commerce platforms;
- Autonomous driving platforms;
- Industrial Internet / Industry 4.0 platforms.

With a high level of diversity and competition between OEMs, suppliers, smart phone network providers, providers of artificial intelligence technologies dedicated to connected and automated driving, mobility services platform, supply chain platforms of logistic specialists and new IoT platforms, Europe represents the first market for connected and autonomous vehicles.

However, European platforms are not at scale given the market fragmentation and the advance of the key US digital platforms.

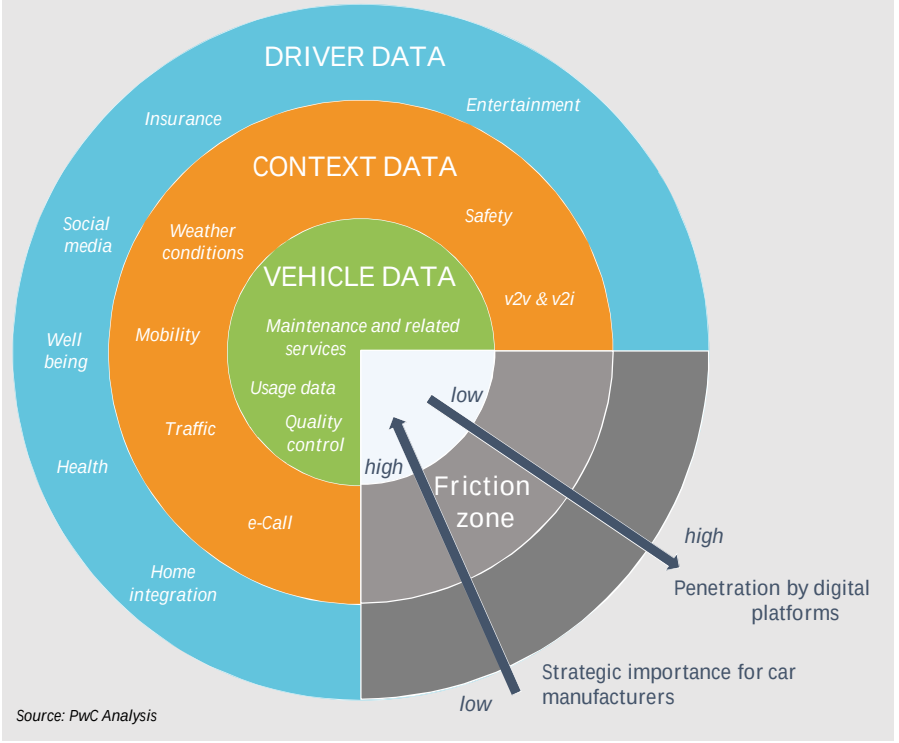
## Keeping a strong and independent European economy

Various studies predict the predominance of digital platforms, as they manage and control their client data. With real time user and client data, these platforms can predict customer needs, suggest products and services and help customise products creating a long lasting and intimate relationship.

The risk of dependence on strategic data and the risk of losing a significant part of the value chain of the European automotive industry to the benefit of non-European digital platforms is very high.

With the acquisition of Here, the consortium of German auto manufacturers has clearly manifested the strategic importance of being independent on maps and navigation operating systems.

Figure 6: Digital platforms capturing the value creation of connected vehicles




Source: PwC Analysis

## Supporting the creation of winning European digital platforms

Large manufacturers and OEMs have created their own internal platforms or acquired emerging platforms on new domains such as BMW for car-sharing.

The creation of a growth and investment strategy for European platforms to scale at a comparable size to that of American and Chinese platforms will represent a major policy to improve the competitiveness of European industry.

### Moving forward

✓ ❻ Support the creation of European digital platforms and help them seize the opportunities to scale up and ultimately become globally leading digital platforms

4

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# Redefining the healthcare industry with big data and digital platforms

A

## The potential of big data for better, smarter and faster healthcare solutions

Like the automotive industry, the healthcare industry has also entered the new digital era. big data and digital platforms are bound to revolutionise the industry with the entire patient experience currently being redefined. In the last years, healthcare service providers, pharmaceutical companies and medical device manufacturers have started to embrace these new technologies by collecting large amounts of health but also routine enterprise data.

The opportunities that big data offer to the healthcare industry are countless. Big data has the power to transform it into a performance and real evidence driven industry for the benefit of the society as a whole.

### Latest digital developments

#### *Towards digital communication*

Digital communication is increasingly becoming a standard feature of the healthcare landscape. Due to the roll out of broadband mobile and fixed networks, patients are closer than ever to medical staff. Besides, the digital interaction between healthcare professionals allows them to share their knowledge and learn from one another.

#### *Explosion of digital devices*

With a global market size that stands at USD 375 billion, the medical technology industry is an eminent part of the healthcare industry.[29] Like other industries, it has also embarked on the digitalisation journey. Mobile and interconnected medical devices able to monitor and transfer data on various vital functions, such as heart rate and blood pressure, are becoming more prevalent.

In 2019, 2/3 of US hospitals will offer digital self-scheduling, delivering $3.2 billion in value[30]

#### *Digitalisation of the whole industry and value chain*

Over the last years, a series of new services and applications has emerged. Examples include:

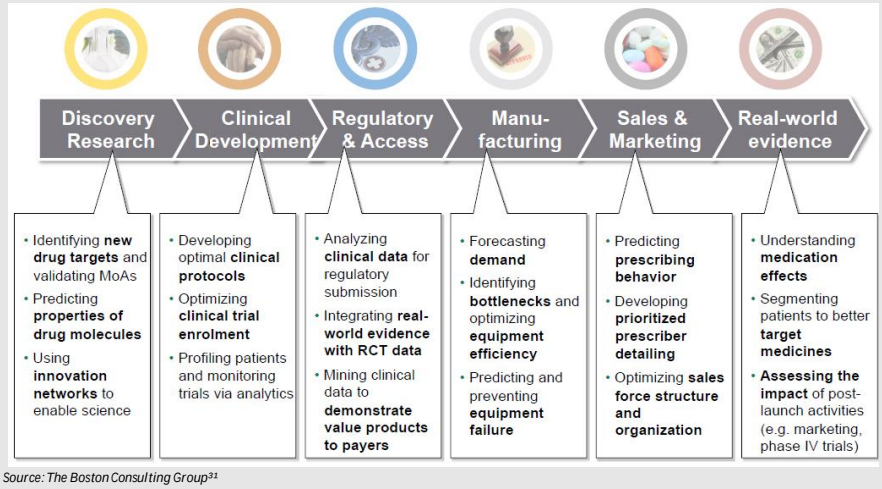
- Health IT: Groups applications used by healthcare professionals, most often in healthcare facilities such as hospitals and doctors' cabinets.
- E-healthcare: Includes mainly what is commonly referred to as tele-health and tele-medicine, allowing for remote interactions between doctors and patients.
- E-selfcare: Applications that allow patients to check their health without medical supervision by keeping track of calories consumed or obtaining data whilst jogging for example.
- Electronic health (EHR) or medical record (EMR): Contains a patient's medical history including diagnoses, medications as well as laboratories and test results.

If properly integrated, these applications and services have the potential to redesign the entire value chain and create more value. Big data and analytics will have to be at the forefront and the ability to convert the mass amounts of raw data into valuable insights will be the most essential piece of the puzzle.

### Improving drug development processes

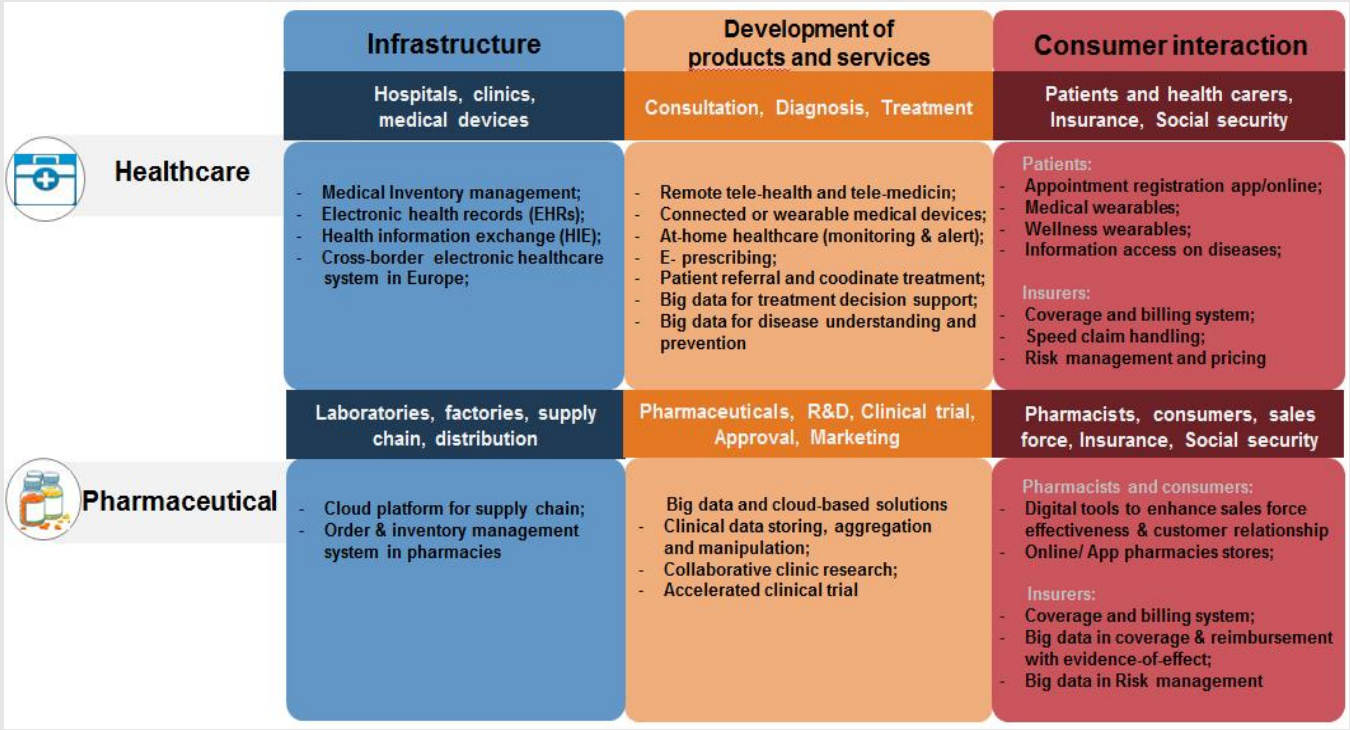
As illustrated in Figure 7, big data and digital platforms offer key opportunities to extract more value across the whole value chain. Essentially, drug development processes will become more cost-effective as big data and digital platforms offer the possibility to maximise the use of data and create new knowledge and insights.

Figure 7: Key opportunities across the value chain




*Source: The Boston Consulting Group[31]*

Figure 8: ICT solutions by segment




*Source: IDATE analysis*

*Increased speed of new drug discovery*

Technology advances have accelerated the discovery and development of new drugs. Thanks to the ability to search in large datasets, big data analytics can quickly identify the relevant information from clinical trials, patients' data, and scientific articles.

For example, clinical trials have proved to be a bottleneck for many researches. They are expensive and hard to manage. Big Data and digital platforms have the potential to remove this barrier by supporting the identification of suitable profiles for the research. Predictive analysis can also help to anticipate potential unwanted side effects.

*Placing patients at the heart of drug developments*

Treatments are moving away from "one-size fits-all" to targeted medication for patients. Big Data is enabling the rise of personalised medicine, based on genomic sequencing, medical sensor data, and electronic health records. Specific drugs for specific patients cohorts are decided based on the trends and patterns identified by Big Data. This personalised approach to treatment is proving much more efficient to curing the patients' diseases.

A large part of a treatment's success lies in its suitability to the patient. Thus, by understanding the patient behavioural patterns, the industry can tailor the treatment to ensure its efficiency. Wearable technologies and medical sensors allow the gathering of such data, to be further exploited through big data analytics.

### A more efficient and effective healthcare system

The cost of healthcare has grown exponentially in Europe. The rise of big data and digital platforms offers unprecedented opportunities to reduce costs but also improve care outcomes.

*Detecting where efforts should be made to increase efficiency*

Big Data and other ICT solutions can help reducing health care expenditures for healthcare providers by analysing and detecting where efforts should be made to improve the efficiency of the healthcare system. In this sense, Big Data analytics can enable yearly profits of USD 300 billion in the US healthcare system. Two thirds of this amount were achieved through reductions of approximately 8% in national healthcare expenditures.[21]

*Better and cheaper medical treatments and interventions*

As mentioned above, big data can help improving processes and especially the detection of diseases. The analysis of multiple patients' data can allow for early detection of diseases, avoiding thus expensive medical examinations, and possibly surgical interventions.

Big data can help avoiding human errors and also help doctors to make better medical diagnosis. In addition, it can allow for better prescriptions in terms of drug choice and treatment duration, therefore limiting the costs of a treatment. For example, advanced big data analytics such as IBM Watson Health solutions will allow the analysis in context (e.g. medical literature and evidence-based guidelines) of both structured and unstructured data. These new insights will bring a new level of confidence to physicians.

In addition, the use of wearable medical devices will provide doctors with real-time information that will allow for more accurate diagnostics.

B

# Navigating in a complex and evolving regulatory framework

## A more efficient and effective healthcare system

### *A fragmented European regulatory framework*

Healthcare data are very sensitive and require an efficient protection. In all European countries, different regulations on data protection and rules have been enacted, creating a very complex environment for companies and researchers. Each time they want to expand their activities in another Member State, they incur costs to understand and adapt their business models to comply with the national rules.

The protection and cybersecurity rules that govern the storage of and access to EHR are a good example of how diverse these rules can be. For example, special schemes have, been developed in France in order to verify the security of hosting systems for personal health records.[32] In Germany, it is forbidden to use EHR across organisational boundaries. In the United Kingdom, data have to be stored in the national territory and cannot be stored abroad.

According to Oracle[33], 29 million patient records were compromised by security breaches between 2010 and 2013 in the US. Still, the actual patchwork of national legislations on data protection and security clearly limits the deployment of big data in Europe.

This complexity adds to the difficulties that pharmaceutical firms already encounter at market entry level. In the EU, market access for new medicines is still frequently granted at country level, following a set of rules that are often country specific. In order to be able to sell a new product in different European countries, firms must comply with different regulations. The cost of adjusting each regulatory dossier to the regulations in place in each country may be prohibitive. This fragmentation is another costly administrative burden that makes it more difficult for many firms, especially SMEs, to access new markets.

### *Increased pace of technology development*

Traditionally, laws and ethical practices have evolved over centuries. Yet today, the rapid pace of technology development requires their change almost immediately. Gaps between regulatory frameworks and innovative products or services are therefore not rare, as illustrated by the case study in Box 2.

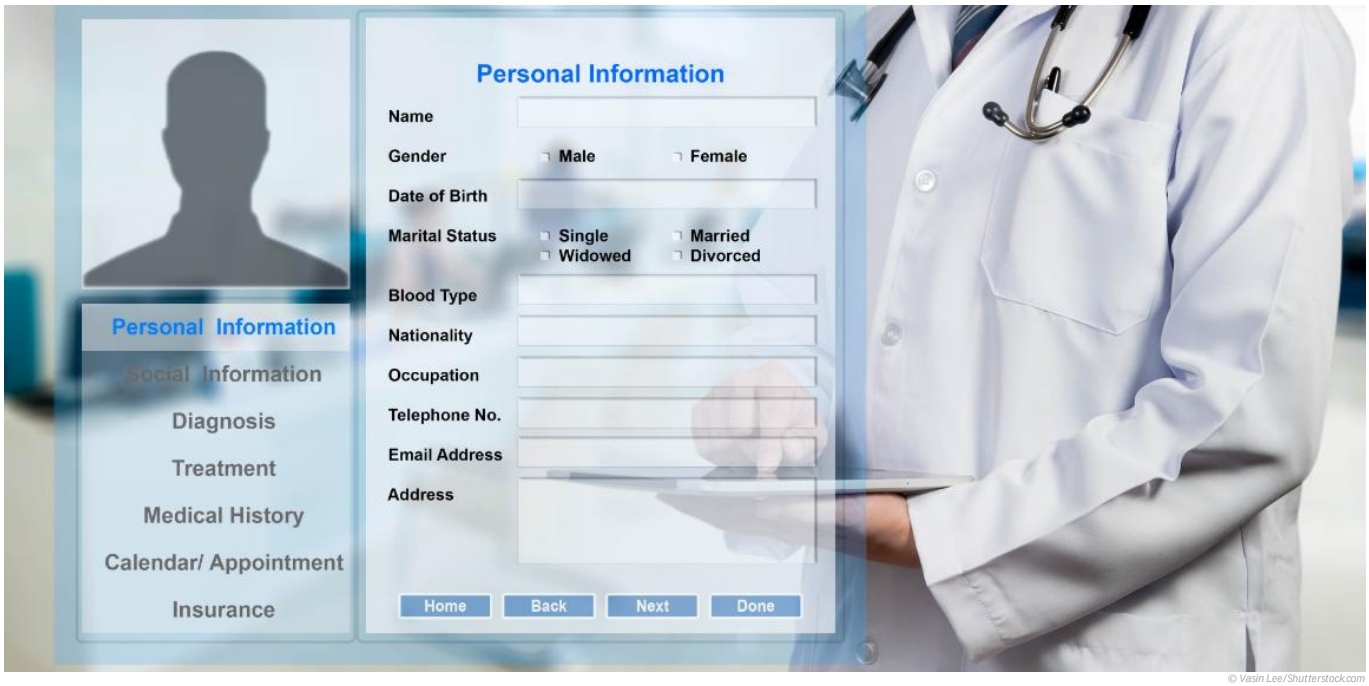
**85%** of doctors say that the use of wearables helps patients to engage more with their own health[34]

### Box 2: Medical Devices Directive

Medical devices have to follow the medical device directive 93/42/EEC (MDD). The MDD provides definition and classification of medical devices and is the basis for a harmonised legislation for safe and effective medical devices.

As technological progress rapidly moves forward, it is sometimes unclear how novel technologies, are regulated. For example, stand-alone softwares, that is softwares that are not part of an existing medical devices, are regulated differently depending on whether they are categorized as medical devices or not.

In 2012, the European Commission presented two legislative proposals for EU Regulations, on medical devices and in vitro diagnostic medical devices. These regulations would replace the MDD, with the principal aim of guaranteeing greater safety. An agreement on the two regulations, currently being discussed with the Council and the Parliament, is foreseen for mid-2016. As part of the ongoing effort to align policies with innovation, a comprehensive review of the MEDDEV 2.1/6 Guidance will also be undertaken. Currently, this guidance covers the qualification and classification of standalone software used in healthcare. The updates will introduce software-related definitions in response to the changing technological environment.



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### Simplifying the rules and promoting responsible data sharing

Healthcare service providers and pharmaceutical companies can grasp the unprecedented opportunities that big data offer only if efforts are made to ensure a well-managed flow of patients' data and research across Europe.

*Towards EU harmonisation: the EU data protection reform*

In December 2015, the European Parliament and the Council agreed on the EU Data Protection Reform that had been put forward by the European Commission in January 2012. This reform modernises the Data Protection Directive proposed in 1995, before mass internet adoption. One of the two instruments of the reform is the General Data Protection Regulation (GDPR). The new regulation aims at establishing a single-, pan-European law for data protection. By eliminating the need to comply with different data protection laws when doing business across borders, businesses will be able make the most of the opportunities of the Digital Single Market.

*Establishing a framework for responsible data sharing*

Beyond the legal barriers, there is a need to involve all stakeholders to agree on a common framework for data sharing. This is the mission carried out by the Global Alliance for Genomics and Health (GA4GH). According to the GA4GH, current frameworks rely on the principle of protection from harm.

The GA4GH aims to promote responsible data sharing. Their framework applies to the use of data as consented to by donors (or their legal representatives) and/or approved for use by competent bodies or institutions. It is based on the following core elements:

- Transparency;
- Accountability;
- Engagement;
- Data quality and security;
- Privacy, data protection and confidentiality; and
- Risk-benefit analysis.

### Providing guidance to the industry to clarify the regulatory framework

With legal barriers slowly being removed, Big Data has a bright future in the health sector in Europe. However, the regulatory framework remains complex. For many firms, particularly SMEs, navigating through the complex web of regulations is still a challenge, and is likely to stay that way. Providing them with clear guidance, for example on how to comply with GDPR to fully grasp the benefits of big data, is certainly the next step to take.

**Moving forward**

- ✓ ❶ Simplify the rules to responsible data sharing
- ✓ ❷ Provide enterprises with clear guidance on how to comply with GDPR efficiently to fully grasp the benefits of big data

C

## Deploying big data to get performance up and costs down

### An industry facing financing challenges

*Dramatic increase of R&D costs*

New molecular entities are at the source of most pharmaceutical breakthroughs. Back in 2003, the average cost of successfully developing a new molecular entity, including R&D spending on failed drug projects, was estimated at EUR 707 million. R&D costs per new molecular entity have grown significantly in recent years for different reasons. Failure rates in clinical trials have increased because of greater research challenges and a willingness to include riskier molecules in such trials. Besides, firms increasingly focus on chronic illnesses, which require larger and longer clinical trials. Finally, the more complex research technologies and the end of the trial-and-error approach in identifying potential drug candidates have also helped to raise average R&D costs.[35]

For the first time, an efficient data curation can be envisaged in clinical trials thanks to big data. Big data will help increase the chance of success and reduce risks in clinical trials, thereby decreasing the costs.

*Difficulty in attracting private and public finance*

While pharmaceutical companies used to focus on the discovery phase of the drug discovery process, they increasingly let early stage research in the hands of smaller, biotech companies to concentrate their efforts on bringing new products to the market.

Biotech companies rely heavily on venture capital and public funding to support the development of their novel solutions and expand their activities. Yet, they encounter more and more difficulties to attract external sources of capital. They are regularly confronted to risk averse investors who typically want to see an attractive proof of concept before deciding to provide capital. Current public funding schemes in Europe have also been criticised for the administrative burden they entail, particularly for SMEs.

### Improving the access to European health data

As mentioned above, the uptake of big data by pharmaceutical companies could lead to more cost-effective drug development processes. By leveraging the diversity of available molecular, genetic and clinical data, predictive modelling of drugs and biological processes can help increase the odds of identifying new molecules that are likely to be effective against the target disease for example. The creation of pan-European databases of high quality data would be a valuable asset for the European healthcare system and health related research.

*Access to European clinical trials data*

The EU Clinical Trials Register is an initiative launched in 2011 by the European Medicine Agency. For the first time, information on clinical trials for medicines authorised in the EU was made publicly available.

*Integrated biobanks*

The Integrated BioBank of Luxembourg Institute (IBBL) has a collection of over 245,000 human samples derived from blood, tissue, saliva, urine, stool and cerebrospinal fluid. By collecting its samples through a unified and strict process that ensures their quality, the institute aims at providing better quality data to researchers.

### Further encouraging the creation of electronic records and storage repositories

The ability to access data generated at all stages of the value chain and beyond is a fundamental requirement to allow pharmaceutical companies to increase the cost-effectiveness of their drug development processes. Initiatives that seek to pool and link health data are mushrooming. Nevertheless, they are seldom connected to one another. Many of them do not go beyond national borders. New initiatives should therefore be promoted, especially at pan-European level.

**Moving forward**

- ✓ ❶ Encourage initiatives that invest in and support the development of pan-European electronic records and storage repositories
- ✓ ❻ Inspire high-potential digital European companies and foster the development of European based digital platforms

**29 million**
patients records compromised by security breaches between 2010 and 2013[3]

D

# Unifying European health data

## Low integration of health data

### *The multiplicity of data generation sources*

The healthcare industry, along with many industries, is generating large amounts of data. Data are produced also by a multiplicity of sources such as wearables and DNA sequencing machines and therefore have different formats. Some are structured data, for example data generated by sensors. Others are semi-structured, like data extracted from social networks.

Regardless of their formats, data have to be combined and analysed in order to provide valuable insights. Data mining and data modelling methods can make sense of these data as long as they are made available and meet quality standards.

Today, these data are largely kept in silos. The different actors in the value chain who produce big data focus on their own market niche and rarely share them with others, thereby creating separate big data pools (Figure 9).

### *The question of trust*

The question of trust is key for the successful uptake of big data. Stakeholders will only engage in data sharing if they trust the quality of data being exchanged. In addition, they must be provided with guarantees against misuse.

### *Lack of standards*

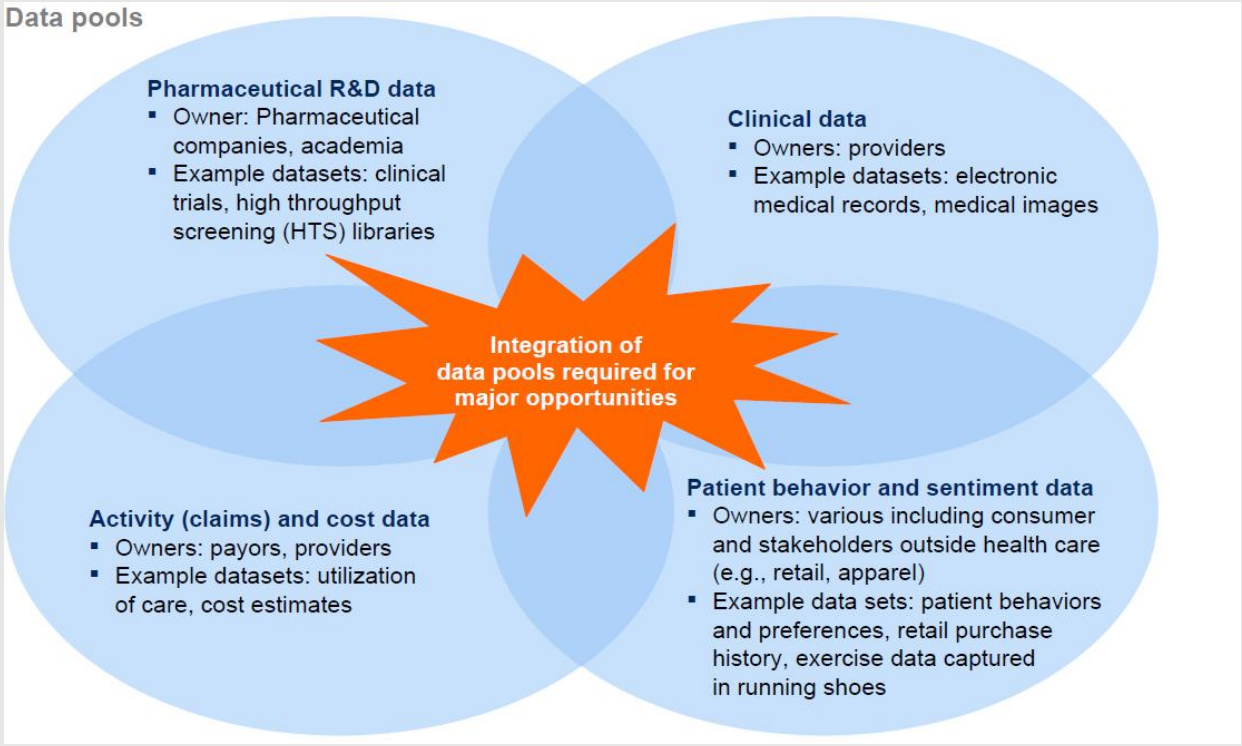
Data are recorded and stored in different nomenclatures and formats, depending on the entity or the country producing it. European data format standards are yet to be developed. They would assure a minimum of interoperability between different data storage systems, and thereby facilitate the exchange of data between organisations and countries.

### *American digital players are more attractive*

While Europe certainly does not lack successful digital companies, many European smart health providers often turn to the US when looking for partnership opportunities to build healthcare digital platforms. This trend is exemplified by the recent announcement of a strategic alliance between Philips and the American CRM company Salesforce.com, as well as the strategic alliance between Sanofi and Google.

Sanofi, a leading producer of diabetes medication, has partnered with Google's

Figure 9: Pools of data created by the healthcare and pharmaceutical industry




*Source: McKinsey Global Institute*[21]

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Life Sciences division to work on a small, connected medical device that would continuously collect diabetes-related data. Both partners are also developing a software that would learn from the information gathered by the device in order to find new treatments. According to the International Diabetes Federation, diabetes is expected to affect 592 million people worldwide by 2035.

## The first steps towards unification

### *Mutual recognition procedures*

Mutual recognition procedures are an answer to the question of trust. They make sure that data are used as intended.

The Nordic countries have an overall population of 25 million potential patients, whereas none of the country have a sufficient critical mass. These countries have a leading position in healthcare with companies such as Astra-Zeneca, Leo Pharma, and Nordisk. This position can be attributed to their extensive healthcare records, personal registers and human sample collections.

The need for large datasets to reach statistical robustness and the opportunity to consolidate data sources pushed these countries to adopt mutual recognition procedures. Physicians and researchers can now access information from the other Nordic countries.

### *Development of European standards for data formats*

One key policy lead initiative is the eHealth Action Plan 2012-2020 of the European Commission. This initiative aims at making use of ICT to improve healthcare in Europe. The Action Plan focuses on developing common standards to enhance interoperable healthcare systems among Member States and the interoperability of EHR between the US and the EU. As this year marks the mid-point of the initiative, an evaluation is due in 2016.

The eHealth Network is another initiative of the European Commission. This network of Member States' officials was set up under the Directive 2011/24, with the objective of working towards delivering sustainable economic and social benefits of European eHealth systems and services, and interoperable applications. The aim is to achieve a high level of trust and security, enhance continuity of care and ensure access to safe and high-quality healthcare. The network is also responsible for drawing up guidelines on:

- data sharing between health professionals to enable continuity of care and patient safety across borders;
- effective methods to enable the use of medical information for public health and research.

Finally, the network is also expected to support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.

As part of its ongoing work, the eHealth Network has adopted a "refined eHealth European Interoperability Framework" in November 2015, replacing the European Medical Information Framework (EMIF), launched in 2013.

### *Private initiatives for standards development*

Besides public institutions. private and non-profit organisations worldwide also work on the development of comprehensive frameworks and related standards for the exchange, integration and retrieval of electronic health information that support clinical practice and the delivery of outstanding health services. Here are some examples of standards still in development: HL7, DICOM, ICPC, and ISO TC 215.

## Encouraging the development of digital platforms and ensuring the interoperability of electronic records systems and data quality

The uptake of big data in the whole healthcare industry will soon be reality considering the number of initiatives that aim at stimulating and facilitating their use. Yet, and in line with the findings of other studies, a lot of work remains to be done on data quality and standards.[32] In particular, the creation of European digital platforms should be encouraged to limit the risk of a European healthcare system driven by data and algorithms sourced outside the EU. Finally, it will be crucial to develop a manageable system of digital identities to ensure the traceability in the data exploitation, thereby ensuring the development of trust.

European standards are likely to become reality considering the number of recent initiatives that promote their development. Still, the road ahead is challenging, particularly because agreements will need to be reached for a variety of data, ranging from medical images, biometric sensor readings and human genetics to population data genomic sequences.

### Moving forward

- ✓ ❶ Support the development of standards to ensure the interoperability of data systems
- ✓ ❺ Encourage the creation of a manageable system of digital ID to ensure the traceability of data and avoid data leakage
- ✓ ❻ Inspire high-potential digital European companies and foster the development of European based digital platforms

# Digitalising mechanical engineering

## to boost Europe's competitiveness

5

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A

## Opportunities for the future of manufacturing

Accounting for a large part of the value creation potential of Industry 4.0, mechanical engineering is a broad field covering materials, design, prototyping, quality control, metrology, analysis, machining, and the production, maintenance and operation of machinery and industrial equipment.

### Mechanical engineering: a key sector for Europe's economy

Mechanical engineering represents a key industry for the European economy, as one of the largest industrial sector in terms of number of enterprises, employment, production, and the generation of added value (9.5% of all the production in EU manufacturing industries).[36]

#### *A high potential industry for the future*

With an estimated 36% share of the world market, the European Union is the world's largest producer and exporter of machinery. Estimations show three million employees active in the sector. Furthermore, the outlook for the European mechanical engineering sector is positive, with an expected growth of 3.8% per annum over next the 10 years.

### The rise of smart industry

#### *A chance for European industry*

Europe's industry is central to its economy, with a value added reaching 15% of GDP. However, in the last decades, it started losing ground to the tough competition from emerging markets.

Smart industry is an opportunity that cannot be missed if mechanical engineering in Europe wants to gain a competitive advantage. The objective is to bring the industry share from 15% back to 20% of GDP.

#### *Digital transformation is already ongoing*

Smart industry should not be seen as a trend of the future: it is already happening. The mechanical engineering industry is increasingly digitalising essential functions of its value chain. In addition, it is enhancing its product portfolio with digital functionalities and introducing innovative, data-based services.

### Enablers of smart industry

The key technological enablers underpinning the digitalisation of mechanical engineering and production – as part of Industry 4.0 – include 3D modelling, scanning and simulation, computer-aided design and engineering, cloud-based high-performance computing (HPC), lasers, cyber-physical production systems, robotics, connected manufacturing equipment, and advanced metrology systems.

#### *Cyber-Physical Systems*

Cyber-Physical Systems (CPS) act as enabling technologies and lie at the heart of this radical transformation to smart industry. CPS allow the creation of integrated and self-regulating systems beyond firm- or industry boundaries, which are instrumental in the optimisation of production processes.[37]

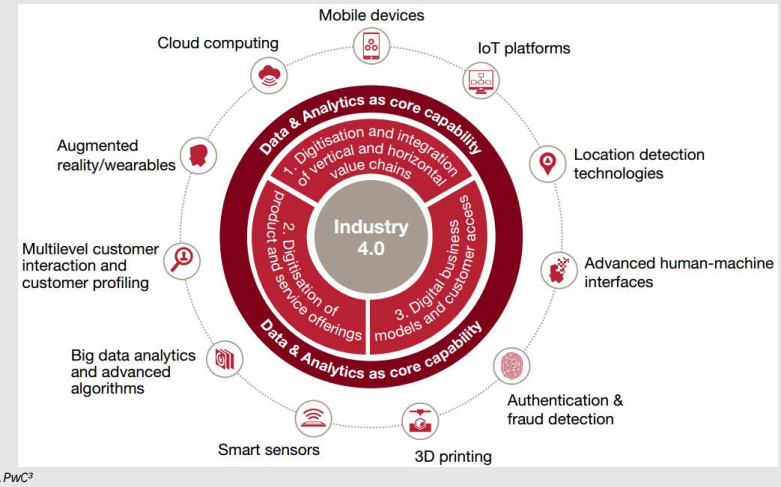
#### *Laser technologies*

The digitalisation of laser control is changing the way products are designed, engineered and manufactured. Laser-based technology, including ultrashort pulse lasers, enables the performance of manufacturing processes in micro ranges, offering increased precision and efficiency, particularly important for the production of, for example, photovoltaic cells and flexible electronics.

#### *Advanced metrology technology*

Metrology (measurement) technologies,, improve the accuracy of data collected during the manufacturing process and enhance the production line's process control features. Metrology technologies[38] are increasingly powerful and sophisticated, providing an unprecedented degree of precision and helping to realise 'zero defect manufacturing'.

Figure 10: Smart industry framework and enabling digital technologies




Source: PwC[3]

## Benefits brought by smart industry

The advantages of smart industry are enormous, including increased productivity, improved resource efficiency, reduced energy use, reduced total machine downtime and maintenance, reduced defects, and reduced time-to-market.

According to McKinsey, smart industry applications whose implementation advanced the most in the last year include: smart energy consumption, real-time supply chain, optimisation, remote monitoring and control, digital quality management, as well as digital performance management. [38]

### *Lower cost and greater efficiency*

Digital transformation of mechanical engineering drives significant leaps in performance. On average, companies are foreseeing a reduction of their operational costs by 3.6% per annum. [3]

### *Quality control*

Big data analytics allow for new real-time quality control solutions to optimise the output. They also identify patterns and relationships among process steps to adjust on yield.

### *Reduced total machine downtime and maintenance*

The introduction of predictive maintenance has allowed the optimisation of the production capacity use. Algorithms are applied to assess the utilisation rate of key assets. This helps anticipate the repair and maintenance schedule to achieve higher asset uptime.

### *Just in time supply chain*

New digital technologies such as CPS-based production chains enable production flexibility and does not require significant changes in existing machines. This provides more scalability, re-configurability and customisation.

## Data is the digital glue

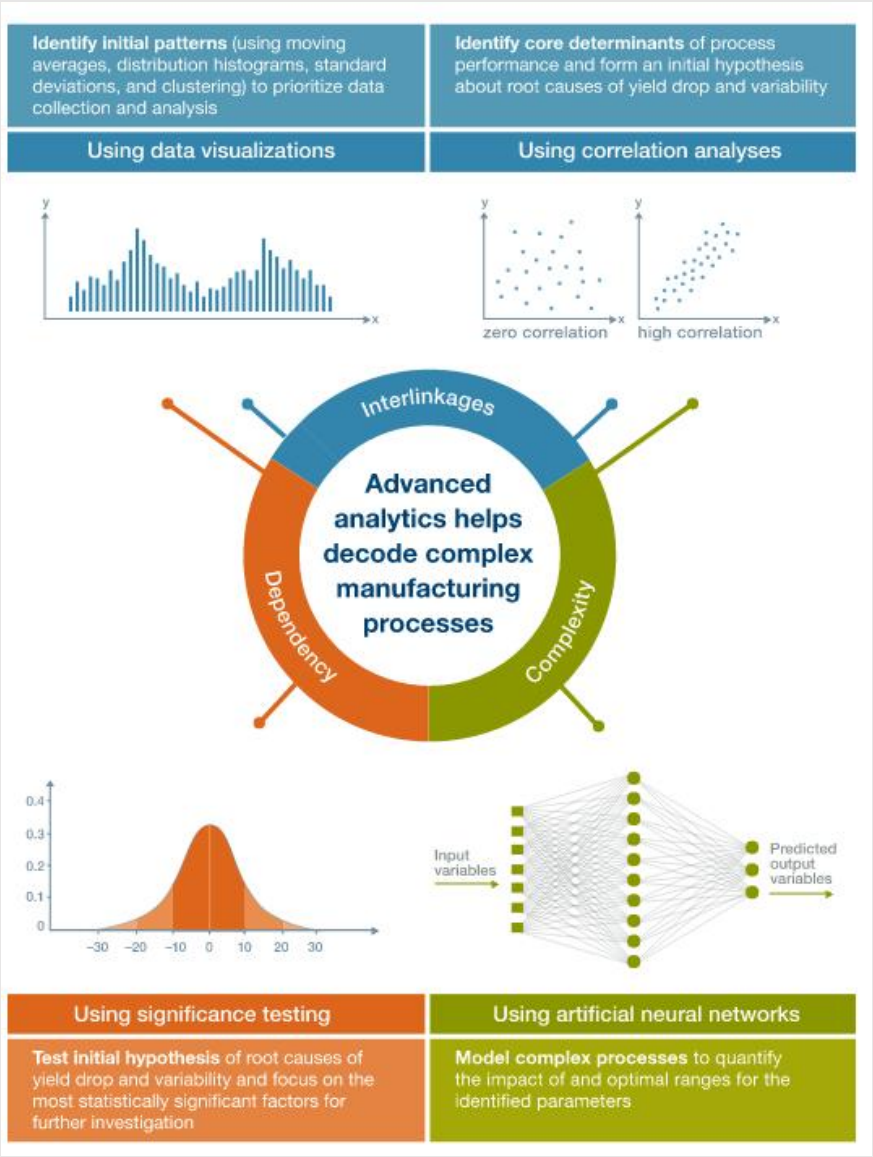
While the key technological enablers of smart industry underpin the digitalisation of mechanical engineering, data is the 'digital glue' or 'digital thread' that connects and ties all the components together.

The EU mechanical engineering sector is expected to grow at an annual average rate of

**3.8%**

over the next 10 years[12]

Figure 11: Advanced analytics applications to mechanical engineering




*Source: McKinsey*[40]

### *A data driven industry*

Smart industry and its technological enablers are, above all, data-driven. The paradigm shifts from the focus on physical assets to the optimisation of how data, treated as a valuable asset, is leveraged, exploited and shared across the entire value chain and products' lifecycle.

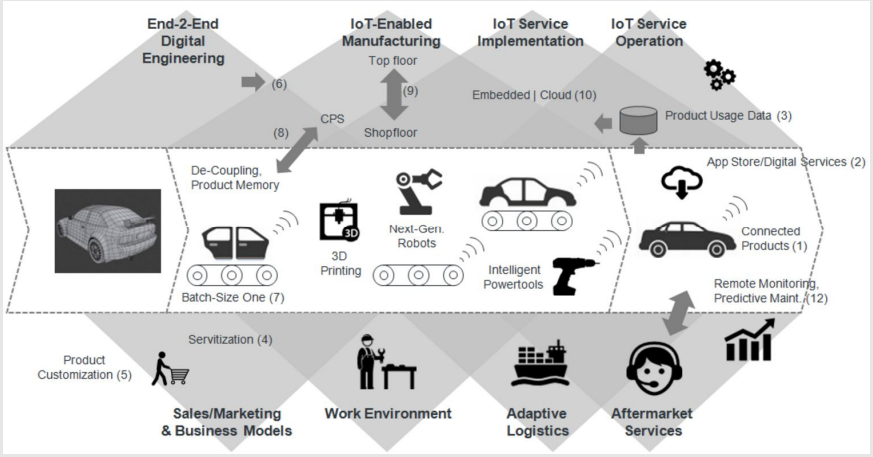
Employees, customers, processes, businesses, products and machines, create massive quantities of data. The generation, collection, processing and sharing of this big data across companies, geographies and system domains, as well as within supply and value chains, and its transformation into smart data, is essential to take advantage of the Industry 4.0 enablers.

### *"Smartisation" of the data*

More than anything else, the market opportunities and the new value potential will be derived from this smart data. The 'smartisation' of the data provides valuable business insights along the entire value chain, optimising collaborative decision-making. Mechanical engineers, for example, will be able to access and exploit data on consumer preferences when taking design decisions.

As digitalisation progresses and automated data acquisition dramatically increases, the amount of data generated grows exponentially. However, simply collecting and storing data has no consequence on mechanical engineering or manufacturing; it is the analysis of the data and the data-driven insights derived that generate an increased productivity, operational performance and value creation.

Figure 12: Industry 4.0 - Data-driven manufacturing value chain




*Source: Enterprise IoT [41]*

B

# Unleashing the flow of data

Explicit and implicit restrictions are detrimental to the development of the DSM, the exploitation of big data, the development of digital platforms and the spawn of smart industry in Europe.

## Harnessing the power of data

The free flow of data in Europe is a fundamental prerequisite of smart industry. Therefore, removing the remaining restrictions on data flows within Europe and removing regulatory barriers is a central part of the Digital Single Market strategy, the Cloud Computing Strategy and the reform of Europe's data protection framework.

## Disparate data sources

Data from the industry is heterogeneous, as it comes from different architectures, systems, platforms, data sources, formats, standards, processes and tools. In addition, the construction of walls around and between business processes and along supply and value chain networks has resulted in silos or islands of information.

Integrating data from disparate sources is the first step to enable smart industry applications. Many smart industry services are built on data from diverse sources and diverse origins.

Gathering this data is crucial to take full advantage of it, yet the sector lacks an industry-wide standard for industrial data generation, transfer and sharing.

## Implementing the GDPR

While the GDPR addresses the fragmentation of national data protection laws, meant to drive the development of pan-European cloud computing and cross-border free data flow, the new GDPR only covers personal data. The non-personal data generated by machines, without any personal identifiable information about physical persons, is mostly unregulated.

## Guidance and clearing on usage of data

While the new GDPR is a positive step forward, there are questions stemming from its implementation at company level. Harmonisation of the regulatory framework is a complex topic for SMEs, which do not have the necessary time and resources to fully comprehend the implications.

Rather than risking stepping out of the boundaries set by law, SMEs tend to limit their utilisation of data. Such limitations are rooted in the perceptions of the institutions and companies involved, relating to the (mis)understanding of the legal and administrative frameworks governing cross-border data flows.

Making the GDPR understandable for everyone is therefore a priority. Clear guidance on usage of data is a mandatory prerequisite to support the uptake of big data technologies for SMEs.

### Moving forward

- ✓ ❶ Encourage initiatives that focus on developing industry-wide standards to facilitate data generation, transfer and sharing
- ✓ ❷ Help SMEs understand the intricate web of regulations by providing them with clear guidance

C

# Building security and trust for IoT

Digital ecosystems in mechanical engineering are challenged by the extensive use of data. The rise of connected devices provide more entry points for potential attackers, which could endanger any company.

## New risk for businesses

Companies are reluctant to take more steps towards big data due to data security concerns. A wide range of issues around data security is preoccupying businesses, including operational disruption due to cybersecurity breaches, liability risks through data loss, unauthorised data extraction within company-internal data flow, damage to reputation, loss of intellectual property.

## Concerns about data sharing

Trust is a key enabler of smart industry. A growing concern in implementing smart industry applications lies in working with third party providers. Companies have proved reluctant to sharing their data outside their internal environment because they fear IT security risks on the partners' side or in transit.

## Digital trust is based on legitimacy and transparency

Cybersecurity is thus a highly limiting barrier to the uptake of the smart industry, and must be tackled. This will happen by ensuring the reliability and effectiveness of new generation security solutions.

These solutions can be introduced as an integral part of all systems and processes related to mechanical engineering. Legitimate third party assurance can play a key role in validating the robustness of such solutions, whose proof of concept should be tested in tough conditions. This will strengthen the trust of stakeholders in the whole ecosystem's integrity.

### Moving forward

- ✓ ❹ Support investments in digital infrastructure, in particular multi-vendor test beds
- ✓ ❺ Develop a European digital identity for industrial digital devices in order to enhance quality control, traceability and trust

# Enabling the digital transformation of SMEs

The uptake of big data and digital platforms in mechanical engineering in general, and the implementation of smart industry solutions in particular, are new to many companies and require considerable investment. Roland Berger estimated that Europe has to invest EUR 90 billion per year in the next 15 years to take the lead in smart industry. This amounts to a total of EUR 1,350 billion.[32]

## Limited investment capacities of SMEs

European manufacturing SMEs are at the core of European growth and industrial renewal. The mechanical engineering industry is characterised by relatively small family-owned companies. It is crucial for SMEs to be equipped with the new tools available to support their activities. However, manufacturing SMEs are significantly slow in catching the digitalisation train.

They often have only limited resources to exploit the opportunities brought by digital transformation. European manufacturing SMEs face immense difficulties to access the necessary financial sources to invest in new technologies and digital mechanical engineering services.

## Heavy upfront investment to take advantage of smart industry benefits

Digital technologies in mechanical engineering require heavy investments. Very often, the entire production capacity has to change to benefit from digital technologies. The major focus of investment is on manufacturing machines, which need to include sensors or connectivity devices, as well as software.

Yet, changing the whole production capacity is a long process. Many machines have extended life cycles and high costs. This prevents SMEs from radically disrupting the production capacity with digital technologies.

Beyond buying the right technologies, companies need to transform their organisation and culture. Businesses need to invest sizeable amounts in training their workforce and hiring data specialists. The investment related to supporting the organisational change should not be underestimated, as it requires long-term change programs.

Europe will have to invest

**EUR 90 billion**

per year in the next 15 years to take the lead in smart industry

### Box 3: Four Member States for a EUR 6bn Supercomputing Project

The rise of smart industry in mechanical engineering asks for supercomputing and data capacities. There is only one European supercomputing facility among the world top 10 supercomputers.

Developing such High Performance Computing (HPC) technology requires several billion euros – a costly endeavor that no Member State can finance by itself.

This is what motivated the Luxembourg government to launch an "Important Project of Common European Interest" (IPCEI) on HPC and big data enabled applications, together with France, Italy and Spain. IPCEIs are large structures that gather knowledge, expertise, public and private resources, as well as economic players across Europe to undertake large-scale, investment-intensive and highly innovative projects.

### Moving forward

- ✓ ❶ Provide SMEs with the tools and competences necessary for their digital transformation
- ✓ ❻ Encourage the creation of digital platforms to facilitate efficient interactions between supply chain actors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# About the Strategic Policy Forum on Digital Entrepreneurship

The Strategic Policy Forum on Digital Entrepreneurship was set up in 2014 to outline what should be the short and long-term strategy for digital entrepreneurship in Europe, to implement this strategy and advise the European Commission on key priorities.
The objectives of the Strategic Policy Forum were to reinforce dialogue between industry, and the scientific and political communities, with the aim of shaping an ambitious EU vision and a European roadmap that will fuel digital entrepreneurship in Europe. The Forum advises the Commission on policy issues and actions to foster digital entrepreneurship and promotes the development of policy by EU countries at national and regional level.

The priority areas to be covered by the Forum's work, include:

- Identifying new business opportunities for jobs and growth: the focus is on how digital tools enable the development of new start-ups in all sectors of the economy, as well as the transformation and growth of existing companies (both SMEs and corporates), including social enterprises and organisations.
- Removing the barriers: the focus is on removing the most significant barriers, at all levels, spanning education, skills and entrepreneurial culture, technology, regulatory issues, taxation, access to finance, etc.
- Raising commitment and actions among the key stakeholders: this includes the public sector, as policy maker, as well as driver and enabler of digital entrepreneurship (e.g. through open government data, public procurement), private stakeholders and public-private partnerships, in support of EU Digital Entrepreneurship policy.

The members are appointed by the Commission, identified among key actors in the digital entrepreneurship field. The European Commission sought to achieve a balanced overall composition, based on broad representation and expertise of the members while keeping the size of the Strategic Policy Forum to a manageable level.

The following key organisations are represented:

- Industry representatives, including digital entrepreneurs, traditional industries (pioneers in the digital transformation of their business), technology service providers to digital entrepreneurs and relevant associations;
- Non-industry/Private organisations supporting and monitoring digital entrepreneurship, including NGOs, trade unions, universities, research organisations, intellectual property experts, equity firms, etc. and
- Public authorities, particularly active in the area of digital entrepreneurship.

### President

- John Higgins, *DigitalEurope*

### Vice-Presidents

- Irene Braam, *Bertelsmann*
- Antonio Murta, *Pathena*

### Members

- Filippo Addarii, *Plus Value*
- Filippo Berto, *Berto Salotti*
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- Daniela Florea, *Geo Strategies*
- Bartlomiej Gola, *SpeedUp Venture Capital Group*
- Blaž Golob, *GoForeSight Institute*
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### Web page of the Strategic Policy Forum on Digital Entrepreneurship

http://ec.europa.eu/ growth/sectors/digital-economy/ entrepreneurship/strategic-policy-forum/index_en.htm

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