



# COCIR **eHEALTH** TOOLKIT

TOWARDS  
DATA DRIVEN HEALTHCARE Fourth Edition  
**APRIL 2014**

**COCIR**  
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry



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### DATA DRIVEN HEALTHCARE FOR MORE EFFECTIVENESS

*Health is our most valuable asset.  
Healthcare is a nation's most valuable institution.  
Innovation is a healthcare system's most valuable pillar.*

Ensuring patients' access to safe, quality treatment lies at the very heart of our European healthcare systems. Our responsibility is to make sure that our healthcare systems deliver on this principle, today and for future generations.

In times of economic crisis and budgetary restrictions, governments and stakeholders need to find new ways to deliver quality care to all. This requires exploring new avenues, thinking out of the box and experimenting with new cost-effective processes.

An important avenue to improving healthcare quality in a cost-effective manner is to leverage modern data driven approaches. There is an increasing amount of health data available, which can be leveraged to support healthcare, research and innovation. Here are some examples, to name a few:

Personalised Medicine holds the promise of better prevention, better diagnosis, better treatment, and less side effects. Big Data and health analytics can help to analyse increasing amounts of health data from different silos in a meaningful way. eHealth solutions can help care providers better manage the medical images and documents accumulated about a patient, for more efficiencies.

Although the benefits of applying these technologies are now widely recognised, the 'data potential' remains mostly untapped today. Industry strongly welcomes the Commission's efforts in the digital and research areas. However we feel more needs to be done at government level to move these promising data driven approaches from the 'nice to have' to the 'must have'. Healthcare systems' sustainability requires a revolution in the way we think, do and deliver healthcare. It requires tapping into the 'data potential'.

The following chapters share industry's insights on how data driven approaches can transform healthcare towards more evidence-based, personalised, and efficient healthcare, with the support of modern data analytics and eHealth tools. The first three chapters outline the potential of Big Data in healthcare, Vendor Neutral Archiving solutions pooling patient data in hospitals and Personalised Medicine. Last but not least, the chapter on data protection explains the healthcare sector's need for data to deliver quality care and medical innovation.

**Nicole DENJOY**  
COCIR Secretary General

## EXECUTIVE SUMMARY

This Toolkit is the fourth edition of the COCIR eHealth Toolkit series.

The first edition of the Toolkit in 2011 set the scene by defining eHealth and developing ten recommendations for better and faster deployment. The following edition issued in 2012 covered important aspects of eHealth such as interoperability, cloud computing and eHealth market development and barriers. The 2013 edition addressed digital hospitals, mobile health, and legal and regulatory trends pertaining to medical software and data protection.

This fourth edition of the COCIR eHealth Toolkit develops the healthcare industry's vision for data driven healthcare. It includes five separate but related chapters on Big Data, Vendor Neutral Archiving, Personalised Medicine, and a critical view on legal and regulatory trends pertaining to eHealth, as well as an updated glossary of terms. All chapters stress the importance of using the growing volume of health data to improve healthcare quality and contain healthcare costs.

The **BIG DATA CHAPTER** describes the benefits of applying modern data analytics to healthcare to store, pool and analyse the growing volume of health data in a meaningful way.

The **CHAPTER ON VENDOR NEUTRAL ARCHIVING** presents innovative trends and solutions that can help care providers share and access medical images and other patient related documents in a seamless way across departments, care providers and care networks.

The **CHAPTER ON PERSONALISED MEDICINE** introduces the paradigm shift from one size fits all to tailored patient centric care. It highlights how adequate eHealth and imaging tools can support this transformation.

The **CHAPTER ON DATA PROTECTION** recalls the importance of data sharing and processing in healthcare to support medical innovation. It calls for a legal framework that fits health and research purposes.

All four chapters propose recommendations for policymakers and healthcare authorities at European, national level and regional level. Some of these recommendations are specific to each topic, but the majority of them are essential to enable the transformation towards data driven healthcare, we therefore summarise them below:

### COCIR RECOMMENDATIONS FOR DATA DRIVEN HEALTHCARE:

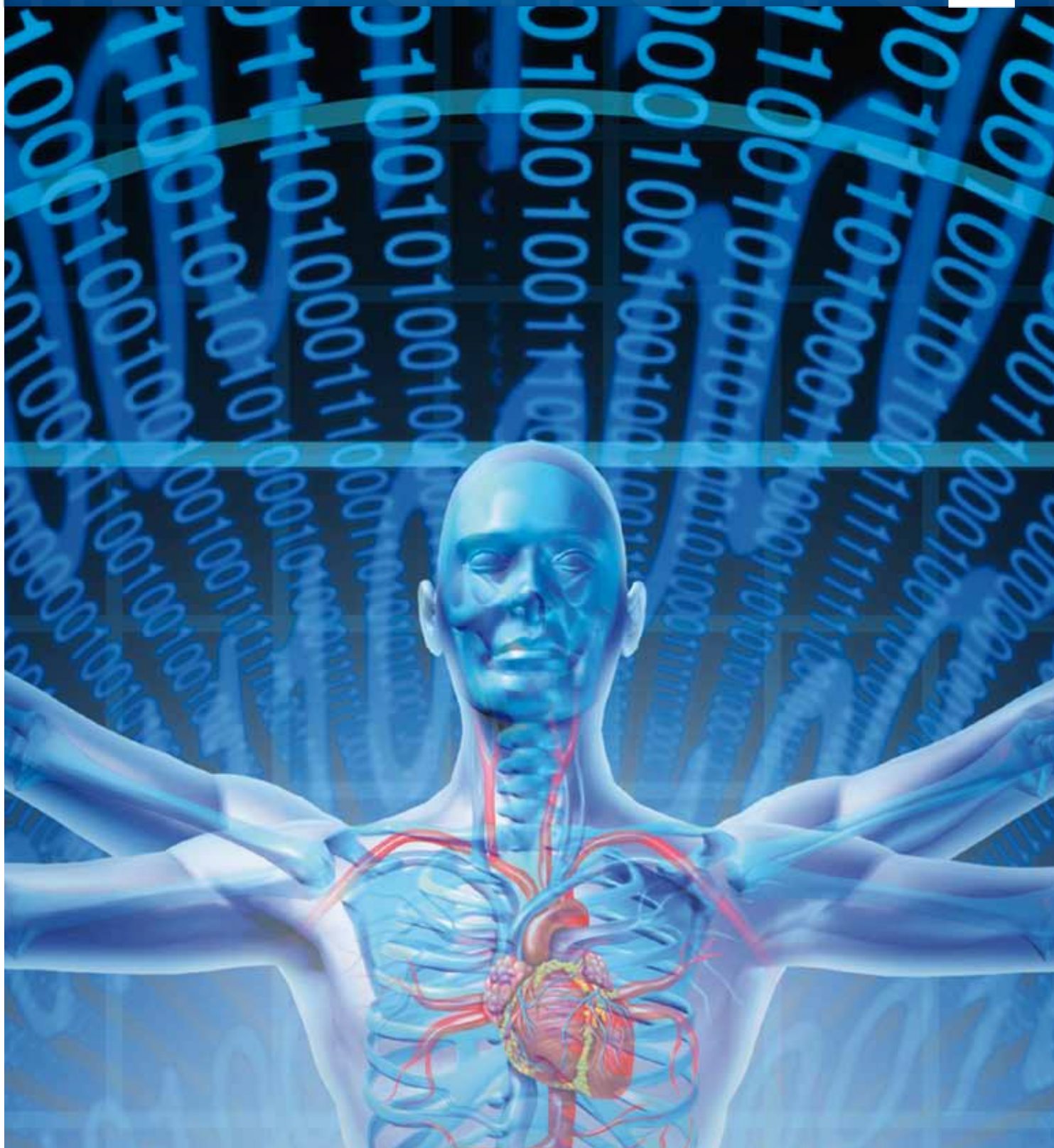
1. Digitise patient records and drive interoperability to ease access to health data
2. Implement Vendor Neutral Archiving within and across care providers for better care coordination
3. Drive Personalised Medicine at EU level to progress towards patient centric care
4. Strengthen IT skills in healthcare
5. Adopt a legal framework that enables data sharing and processing for health and research purposes



# BIG DATA

HOW ANALYTICS CAN ADD VALUE  
TO HEALTHCARE

# 1



## PART 1 BIG DATA

# 1

### HOW ANALYTICS CAN ADD VALUE TO HEALTHCARE

WHAT IS BIG DATA? .....	5
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Big Data can help us capitalise on patient data to enable healthcare innovation, support medical research, improve therapies and inform public health policies.

All the conditions are now met for exploiting Big Data in healthcare: an increasing volume of health data is becoming available<sup>1</sup>; technical advances make it easier to collect and analyse information from multiple sources; and fiscal pressure calls for more effective and cost-efficient healthcare.

The European Council recognises this in its October 2013 Conclusions<sup>2</sup>, which stress that “*Europe must boost digital, data-driven innovation across all sectors of the economy*”, and identifies Big Data as a “*strategic technology enabling productivity and better services*”. COCIR fully supports that view and encourages the healthcare sector to invest in Big Data.

However, policy and legal environments need to be adapted if we want to reach the full potential of Big Data in healthcare. Policies dealing with Big Data need to find the right balance between three fundamental values: the need to protect personal data, the need for open access to data for research purposes and the need to create a competitive and vibrant industry in Europe. This paper is an introduction to Big Data in healthcare covering the definition, benefits, challenges and policies that are required to benefit from the possibilities offered by Big Data.

#### COCIR RECOMMENDATIONS

1. Create an interdisciplinary body to explore jointly the applications, benefits and risks associated with Big Data
2. Continue efforts to promote open and standardised data
  - Share results of clinical trials in an exploitable format
  - Promote the adoption of international consensus standards
3. Invest in Electronic Patient Records and interoperability
4. Strengthen IT skills in healthcare
5. Adopt a regulatory framework that allows access to data:
  - Promote a pragmatic, flexible, future-proof legal framework
  - Allow the secondary use of data for health purposes
  - Allow transfer of data to non-EU countries

1. Pharmaceutical companies share results of their clinical trials, care providers digitize patient records, governments adopt ‘open data’ policies, citizens share data on social media etc.

2. [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/ec/139197.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/ec/139197.pdf)

## WHAT IS BIG DATA?

Big Data refers to datasets whose size is beyond the ability of typical database software tools to capture, store, manage, and analyse.

Big Data also refers to the management of these ultra-large amounts of information (e.g. storage, aggregation, search, analysis, visualisation, and combination) and the use of the results to extract knowledge.

Big Data in healthcare refers to the ability to capitalise on the growing volume of health data available from different sources to generate healthcare innovation. By making smart use of the ever-increasing amount of data available, we can find new insights by re-examining the data or combining it with other information. In healthcare this means not just mining patient records, medical images, bio-banks, test results, etc.

for insights, diagnoses and decision support advice, but also continuous analysis of the data streams produced for and by every patient in a hospital, a doctor's office, at home and even while on the move via mobile devices.

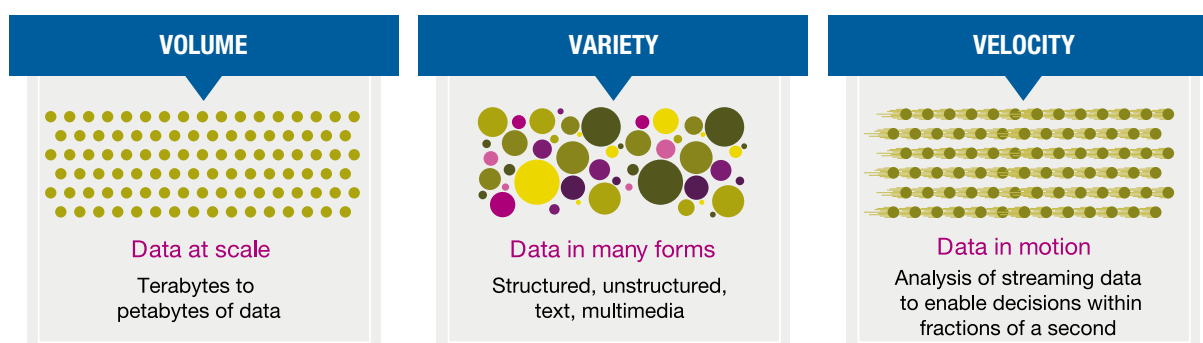
*“Data  
is a precious  
thing”*

*Tim Burners-Lee<sup>3</sup>*

Until recently, these data remained in silos and were not exploited jointly. Today new technology, enhanced connectivity and mobility, allow grouping and analysing disparate data through diverse data analytics techniques. This is a major development for healthcare organisations that can now capture, share, integrate and analyse data across all the ecosystem stakeholders.

A more flexible definition is becoming the norm with the so-called “**3V**”s of Big Data: **VOLUME**, **VARIETY**, and **VELOCITY**.

Figure 1: The ‘3Vs’ of Big Data



### VOLUME

Volume refers to the increasing amount of data available. In 2011, the data glut was estimated to be 150 exabytes (150 million gigabytes) for healthcare globally<sup>4</sup>. Patient records include images, lab test results, clinicians' observations, in future also genetic and –omics data, etc. The size of a single patient medical record can reach 4 GB (excluding images)<sup>5</sup>. However medical records of patients suffering from long-term conditions may reach up to several hundred GB (including images).

Estimates show that 1 billion medical images are generated every year<sup>6</sup> and the amount of medical information available is doubling every five years<sup>7</sup>.

In addition to clinical data, there are high volumes of data from diverse sources: scientific, academic, publications, administrative, insurance claims, social media and genetics.

3. Inventor of the Internet.

4. Healthcare - An overview of the challenges in data intensive healthcare - Edwin Morley-Fletcher

5. <https://blogs.law.harvard.edu/phlg/2013/01/11/electronic-medical-records-dont-save-money/>

6. IBM Global Technology Outlook 2013

[http://www.zurich.ibm.com/pdf/isl/infportal/Global\\_Technology\\_Outlook\\_2013.pdf](http://www.zurich.ibm.com/pdf/isl/infportal/Global_Technology_Outlook_2013.pdf)

7. [http://www-03.ibm.com/innovation/us/watson/watson\\_in\\_healthcare.shtml](http://www-03.ibm.com/innovation/us/watson/watson_in_healthcare.shtml)



## VARIETY

Variety refers to the different types of structured and unstructured data from different sources. While there is exponential growth in structured data originating from administrative systems (e.g. Hospital Information Systems or Enterprise Resource Planning) and clinical data originating from Electronic Patient Records, there are many other sources of data, which as of today are all unstructured – such as a simple puff document. Unstructured data refers to data that is not organised in a pre-defined data model. Estimates indicate that up to 80% of health data is unstructured and stored in silos. Examples include e.g. referral letters, reports, studies, articles etc. as shown in Figure 2. Although some years ago it was impossible to create value out of these data, modern analytical tools and natural language processing systems allow interpretation of these data, unveiling a complete new source of information.

Following the introduction of digital X-Ray systems, the volume of images from modalities has grown enormously. With the advent of digital photography, pictures and movies are increasingly being used in healthcare.

In industrial production and logistics processes, smart sensors have proven to bear great optimisation potential. Applied in healthcare automated distribution, localisation of assets, patients and personnel are among the first solution areas. Data collected can be used to analyse and optimise procedures or for security and surveillance.

Also laboratory studies and examinations including -omics data (genomic, proteomics, etc.) are another upcoming variation of high volume data. Technology development has made sequencing the human genome more affordable; leading to more.

Figure 2: Origins of health data



## VELOCITY

Velocity refers to the speed at which data is created, processed and analysed and the fact that the speed of data processing is accelerating. Velocity impacts latency – the lag time between data creation (and capture) and when it is accessible. Today, data is continually being generated at a pace that is impossible for traditional systems to capture, store and analyse. For time-sensitive processes such as healthcare, certain types of data must be analysed in real time to be of value to the clinician. While some of these data are of a static nature, others are dynamic: they will change permanently and the value of these data lies in their variability and dynamism (e.g. localisation data and longitudinal data series).

**Beside these 3 Vs, some use additional 'V' like Veracity, Validity, Volatility or Value.**

8. <http://www.zdnet.com/within-two-years-80-percent-of-medical-data-will-be-unstructured-7000013707/>

## WHY IS THE BIG DATA REVOLUTION IN HEALTHCARE HAPPENING NOW?

Many factors are coming together to drive the demand for Big Data in healthcare.

Over the last decade, pharmaceutical companies have been aggregating years of research and development data into medical databases; payers and providers have digitised their patient records; governments have opened their health-care knowledge, including data from clinical trials and information on patients covered under public insurance programs.

With healthcare costs rising, fiscal pressure calls for more effective and cost-efficient healthcare, and more evidence on “Paid for Outcomes” rather than “Paid for Service”.

Clinical trends also play a role: the drive for more evidence-based medicine<sup>9</sup>, which involves systematically reviewing clinical data and making treatment decisions based on the best available information.

In parallel to the societal factors outline above, recent technical advances have made it easier to collect and analyse information from multiple sources, enabling the healthcare and research community to link and extract knowledge out of data.


*A McKinsey report<sup>10</sup> estimated that if applied at scale, initial successes of data analytics applied to healthcare could reduce US healthcare spend by 300 to 450 billion\$ per year.*

## MAKING SENSE OF BIG DATA THROUGH ANALYTICS

Data alone do not hold any value. The value resides in the knowledge that can be extracted from the data. A wide variety of techniques and technologies has been developed and adapted to aggregate, manipulate, analyse, and visualise Big Data. These techniques and technologies draw from several fields including statistics, computer science, applied mathematics, and economics.

Figure 3: Three most common data analytics techniques used for health purposes

**DESCRIPTIVE ANALYTICS**



> What happened?  
> When and where?  
> How much?

- Operational, clinical, financial reporting and analytics
- Clinical dashboards
- Clinical research

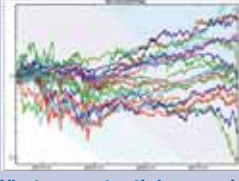
**PREDICTIVE ANALYTICS**



> What will happen?  
> What will be the impact?

- Operational & financial forecasting & optimisation
- Evidence-based medicine
- Personalised medicine
- Patient/population behavior

**DECISION SUPPORT & OPTIMISATION**



> What are potential scenarios?  
> What is the best course?  
> How can we pre-empt and mitigate the crisis?

- Clinical decision support
- Personalised medicine
- Integrated care

9. See definition in glossary of terms.

10. McKinsey – the revolution in healthcare – Accelerating value and Innovation – January 2013.



### DESCRIPTIVE ANALYTICS:

Descriptive analytics is used for ad-hoc analysis and Clinical and Business Intelligence reporting. It answers the questions ‘what happened?’ and ‘why did it happen?’ It looks at past performance/activities and understands that performance by mining historical data to look for the reasons behind past success or failure.

### PREDICTIVE ANALYTICS:

Predictive analytics answers the question ‘what will happen?’ It combines historical data with rules, algorithms, and occasionally external data to determine the probable future outcome of an event or the likelihood of a situation occurring.

### DECISION SUPPORT AND OPTIMISATION:

Decision support and optimisation - also called prescriptive analysis in the business environment - anticipate what will happen and when it will happen, but also why it will happen. Further, it will suggest decision options, and shows the implication of each decision option. Decision support and optimisation can continually take in new data to re-predict and re-prescribe, thus automatically improving prediction accuracy and prescribing better decision options.

Another technique is **STREAMING ANALYTICS**: The traditional way of processing data into information is storing it in a data warehouse and then running analytics programmes over it. Streaming analytics is about processing data in real-time, rather than from a data warehouse. It allows real-time decision-making, which can be very useful in intensive care units, or emergency departments where physicians need to monitor patient data. In combination with predictive analytics, streaming analytics techniques have enormous potential in those situations where instantaneous decision-making based on huge amounts of data or combination of several data types.

*University Hospital for Sick Children, Ontario. A Stream-computing platform was developed to capture and analyse real-time data from medical monitors, alerting hospital staff to potential health problems before patients manifest clinical signs of infection or other issues.*

*It offers clinicians the ability to interpret vast amounts of heterogeneous data in real time, enabling them to spot subtle trends.*

## BENEFITS OF APPLYING DATA ANALYTICS IN HEALTHCARE

Insights derived from the analysis of large-scale health data have multiple applications in healthcare and medical research. Below is a snapshot of how the healthcare system can benefit from health analytics:

### IMPROVE HEALTHCARE QUALITY AND OUTCOMES

Through the use of descriptive analytics, healthcare providers can monitor the efficacy of treatments on certain conditions, compare the safety and effectiveness of treatments, monitor adverse events in relation to medication and use of medical devices, compare the efficiency of different pathways, and adapt where necessary the standard care protocols in use.

For instance, analysing the continuous flow of data coming from remote patient monitoring services can help to monitor adherence to treatment, improve future drugs and treatment options and better understand the evolution of chronic conditions. This data-based ‘intelligence’ allows the healthcare community to define optimal care pathways and to progress towards an evidence-based management of healthcare systems.

### **Using Big Data to reduce medication errors**

*Current clinical decision support systems analyse physicians' entries and compare them against medical guidelines to alert to potential errors such as adverse drug reactions. Deploying these systems, healthcare providers can reduce adverse reactions.*

## **ENHANCE MEDICAL RESEARCH**

Data analytics offer a myriad of advantages for medical research:

- **Clinical trials:** data analytics facilitate the identification of target patients for clinical trials, based on data included in Electronic Patient Records. It also offers robust structures to track the progress of trial participants on the long term.
- **Personalised Medicine<sup>11</sup>:** predictive and prescriptive analytics combine data from various sources (clinical, lifestyle, genomic data) to determine the predisposition of an individual to disease, to tailor the right therapeutic strategy for the right person at the right time, and to deliver timely and targeted prevention. Personalised Medicine can improve prevention; improve treatment efficiency, improve patient quality of life. This also supports a more patient centered approach, as opposed to applying standard protocols to all patients.

*In the United States, the Frederick National Laboratory funded by the National Cancer Institute has been using solutions to support researchers working on the relationship between genes and cancer.*

*In a recent example, they built infrastructure capable of cross-referencing the relationship between 17,000 genes and five major cancer subtypes across 20 million biomedical publication abstracts, and cross-referencing gene expression data from simulated 60 million patients and miRNA<sup>12</sup> expression for simulated 900 million patients. This helped researchers understand additional layers of the pathways these genes operate in and the drugs that target them, and accelerate their work<sup>13</sup>.*

## **FOSTER MEDICAL EQUIPMENT DEVELOPMENT AND MAINTENANCE**

The development, testing, maintenance and post-market surveillance of medical devices require data processing on a continuous basis. Data analytics allow technicians to envisage and visualise possible scenarios in a healthcare episode in order to develop safe hazard-proof equipment.

## **SUPPORT PUBLIC HEALTH POLICIES**

Public authorities collect and process data to detect and model epidemic waves, evaluate the efficacy and efficiency of treatments, make correlation between risk factors and the emergence of diseases (e.g. asbestos and cancer), define population at risks of poor health, and articulate informed-based prevention and public health policies. For instance, prescriptive analytics can be used to anticipate the outbreak of pandemics and define best prevention approaches.

### **Using Big Data to assess effectiveness of drugs and adapt reimbursement schemes**

*The Italian Medicines Agency collects and analyses clinical data on the experience of expensive new drugs as part of a national cost-effectiveness programme.*

*The agency can impose "conditional reimbursement" status on new drugs and can then reevaluate prices and market-access conditions in light of the results of its clinical data studies.*

11. See Part 3 on Personalised Medicine

12. miRNA is a small non-coding RNA molecule (ca. 22 nucleotides) found in plants, animals, and some viruses, which functions in transcriptional and post-transcriptional regulation of gene expression.

13. <http://ctovision.com/2012/11/the-winner-of-the-2012-government-big-data-solutions-award-is-the-national-cancer-institute/>

## FACILITATE INTERNATIONAL COMPARISONS TO IMPROVE OUTCOMES AND PERFORMANCE

Internationally comparable population level health data are leading to new ways to benchmark and compare how health systems are performing to help countries to improve patient safety, health outcomes, and system performance.

*The EU-funded ECHO project<sup>14</sup>, pools data from seven countries to help public health authorities learn more about variation in access to care and outcomes of care and the relationship between this variation and the socio-economic status of patients.*

*"A complex task like decoding the human genetic code - needing analysis of 3 billion base pairs - took ten whole years back in 2003: now it can be achieved in just one week. Thanks to faster processing." Neelie Kroes, European Commissioner for Digital Agenda<sup>15</sup>*

## CHALLENGES OF BIG DATA: LEGAL AND TECHNICAL ASPECTS

### LEGAL FRAMEWORK CATCHING UP WITH DATA SHARING NEEDS

Capturing value from Big Data depends on access to data, often beyond organisations' borders. Stakeholders in the healthcare sector often do not share existing datasets, because of legal constraints such as privacy laws. The current legal framework for the protection of personal data in Europe<sup>16</sup> limits the possibilities for data sharing across borders and organisations and limits processing to the purpose for which the data was initially collected. In addition, data concerning health can be processed for research purposes provided the data has been anonymised and the data subject cannot be re-identified and the data subject has given their consent for a specific purpose.

While these measures aim to protect citizens' privacy, they make secondary use of data for healthcare and research complicated and costly if not impossible. This is regrettable when we consider the knowledge that could be extracted from these data, for the benefit of biomedical research and society at large.

### LACK OF TRUST IN IT SYSTEMS AND RELUCTANCE TO SHARE DATA

Another factor slowing the development of health analytics is the reluctance of many stakeholders to share data. There is a lack of trust with regards to modern ICT and their potential for intrusion, data theft, data alteration etc. COCIR acknowledges that these fears need to be addressed as eHealth, cloud computing, Big Data, and other promising technologies will not develop without citizens' trust.

#### Security measures:

Big Data companies and other ICT infrastructure providers (e.g. hosting) develop and invest in state-of-the-art security measures to strengthen data security, and have put policies and controls in place to maximise data security and privacy. However no matter how hard we try to limit the risks, 'zero risk' does not exist. In addition, COCIR notes that for certain aspects, including hosting, numerous regulatory discrepancies between the various Member States, lead to fragmented and uncertain legal environments.

14. European Collaboration for Healthcare Optimisation : <http://www.echo-health.eu/>

15. [http://europa.eu/rapid/press-release\\_SPEECH-13-893\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-13-893_en.htm)

16. Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>



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**Risk-based approach:**

Therefore regulations should not try to reach the illusion of ‘zero risk’. A risk-based approach would be a more pragmatic choice, weighing the benefits and risks of data sharing. COCIR is of the opinion that the benefits of medical innovation for society outweigh the risks associated with the use of patients’ data by health professionals<sup>17</sup>.

**TECHNOLOGICAL CHALLENGES: RELIABILITY AND STRUCTURE OF DATA**

A major challenge is the reliability and quality of the data itself: its value and usability in context. Striving for high data quality is an important requirement and challenge, but even the best data cleansing methods cannot remove the inherent unpredictability of some data.

Another significant challenge is the lack of integration of existing data pools.

The fragmentation between the data repositories (epidemiological and registry data, clinical data, claims data, pharmaceutical and research data, patient behaviour and sentiment data<sup>18</sup> etc); the overwhelming majority of unstructured data, the multiplicity of incompatible data formats for the structured data, constitute considerable hurdles to integrate these data points and apply sophisticated analytics that create value from Big Data. It will be imperative for IT service providers and healthcare organisations to overcome technology barriers to enable the sharing of data.

**STRUCTURAL CHALLENGES: LACK OF IT VISION IN HEALTHCARE SYSTEM**

A significant constraint on realising value from Big Data is the shortage of IT and adjacent skills in healthcare organisations. Using Big Data requires a multidisciplinary approach gathering various profiles (e.g. clinicians, IT engineers, statisticians, researchers, bio-informaticians, mathematicians etc) is needed to pool the skills necessary to analyse and understand Big Data. This calls for a new mindset in healthcare systems, the insertion of IT modules in medical curricula and the training of medical staff.

Last but not least, the deployment and meaningful use of Electronic Patient Records in healthcare organisations remains too low. Electronic Patient Records provide a major foundation for pooling single patient-related data in standardised formats and supporting comparative effectiveness research into drugs and treatments.

**LACK OF ROBUST BUSINESS MODEL**

Applying data analytics in healthcare has a cost which calls for return on investment or more precisely for a “return in outcome”. Preventive diagnostic and therapeutic regimes that prove a higher sensitivity and specificity and thus a better outcome should be rewarded. However healthcare is a complex eco-system and transforming a pay for service into a pay for outcome business will only arise through a payer reform.

- Payers will only pay for outcome and proven evidence and no longer for service
- Providers might gain higher margins as they reduce the number of readmissions and associated penalties
- The pharmaceutical industry may speed up translational research and may develop drugs more specifically targeted to patients’ diseases
- Patients might benefit from higher efficacy of prevention, diagnosis and therapy.

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17. See Part 4 on Data Protection

18. An emerging pool of data related to patient behavior (e.g., propensity to change lifestyle behavior) and sentiment (e.g., from social media) that is potentially valuable but is not held by the healthcare sector

## COCIR RECOMMENDATIONS TO CAPTURE THE VALUE OF BIG DATA IN HEALTHCARE

Big Data could help transform healthcare as delivered today into value based healthcare tomorrow, but the right framework is needed to capture its value. Member States, the European Institutions and healthcare providers will need to overcome challenges related to technology, data access, skills and changing mindsets in the healthcare sector. COCIR recommends:

### 1. CREATE AN INTERDISCIPLINARY BODY AT NATIONAL LEVEL TO EXPLORE JOINTLY THE APPLICATIONS, BENEFITS AND RISKS ASSOCIATED WITH BIG DATA

Exploiting Big Data requires cooperation between different sectors: healthcare providers, public health authorities, academics, medical research, industry and more. Dialogue and concrete actions need to take place to understand what modern data analytics techniques can bring to each sector, what the potential risks are, how to create synergies, and how to invest in the right structures and resources to maximise the outcomes of Big Data.

### 2. CONTINUE EFFORTS TO PROMOTE OPEN AND STANDARDISED DATA

Commissioner Vice President Neelie Kroes rightly said 'Knowledge is the engine of our economy and data is its fuel'.

- COCIR strongly welcomes the Commission's drive to open government data and also strongly encourages health organisations to make their data freely available. For instance, providing access to clinical trial results in an exploitable format would bring tremendous benefits to healthcare and medical research.
- COCIR also urges Member States to adopt much faster international standards for clinical information and implement Electronic Patient Records and other health databases. This will increase data reliability, reduce data analysis cost, and increase outcomes for healthcare providers.

### 3. INVEST IN ELECTRONIC PATIENT RECORDS AND INTEROPERABILITY

Deployment and adoption of Electronic Patient Records is still low at healthcare providers. Providers will have to invest in deploying Electronic Patient Records systems much faster to capture and store clinical data in an efficient, standardised and cost-effective manner.

### 4. STRENGTHEN IT SKILLS IN THE HEALTHCARE ECOSYSTEM

Healthcare providers and policymakers will need to develop a new generation of IT skilled workforce in the health sector. This calls for:

- Training a new generation of health data scientists
- Educating healthcare professionals and researchers on data analytics
- Introducing IT and data analytics courses in medical curricula

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## 5. ADOPT A REGULATORY FRAMEWORK THAT ALLOWS ACCESS TO DATA

As using Big Data becomes important to the healthcare industry, policymakers will have to reevaluate privacy laws to ensure data is available in a safe and secure way. Europe needs a pragmatic, flexible, forward-looking and future-proof legislative framework that can keep step with technology and protect citizens' privacy without hindering innovation and medical progress. Any data protection philosophy should balance the benefits versus the risks.

- The data protection regime in Europe should allow for the secondary use of data for health and research purposes with adequate safeguards.
- COCIR suggests revising the conditions for explicit and purpose limited consent as they will unavoidably limit data sharing and processing for research purposes. The notion of 'broad consent' would be a more pragmatic approach without increasing privacy risks.
- The data protection regime should allow transfers of data towards third countries where adequate safeguards are in place. Research increasingly builds upon international cooperation, such as in large-scale trials that may need several thousands of records. It also avoids duplicating research efforts and ensures best use of public financial means.





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## NOTES

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# VENDOR NEUTRAL ARCHIVING

IMPROVING MEDICAL IMAGE AND DOCUMENT SHARING  
FOR BETTER CARE COORDINATION





## PART 2 VENDOR NEUTRAL ARCHIVING

# 2

### IMPROVING MEDICAL IMAGE AND DOCUMENT SHARING FOR BETTER CARE COORDINATION

WHAT IS VENDOR NEUTRAL ARCHIVING (VNA)?	17
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Regional Health Imaging projects vary in their complexity and target functionality. They range from simple centralised archiving systems to a complete regional imaging shared workflow unifying the patient record across regions, care providers and departments, creating a longitudinal patient-imaging record by integrating and linking images. An increasing number of such projects enable the sharing of documents such as structured laboratory reports, patient summaries, medication prescriptions and dispensations, content well beyond images, from various departments, specialties and care providers, at the regional or national level.

COCIR members have gained significant experience in delivering regional and national imaging networks across the globe. To align the expectations among all stakeholders and ensure unambiguous definition of key target functionalities, COCIR vendors took the initiative to provide a clear definition of Vendor Neutral Archiving (VNA) to address the challenges VNA responds to and to document its various components and benefits.

This paper provides an overview of the current state and future direction of the VNA market. It describes the key drivers of the VNA market, assesses the evolution of VNA solution as well as its key components and features. The paper also shares insights on the VNA market size and provide a five-year forecast towards 2017. Last but not least, the paper articulates recommendations to maximise the impact of VNA deployment in regions and clusters of hospitals.



*Regional and National Imaging Sharing Network*



## COCIR RECOMMENDATIONS

COCIR recommendations for better implementation of VNA across medical imaging and care providers:

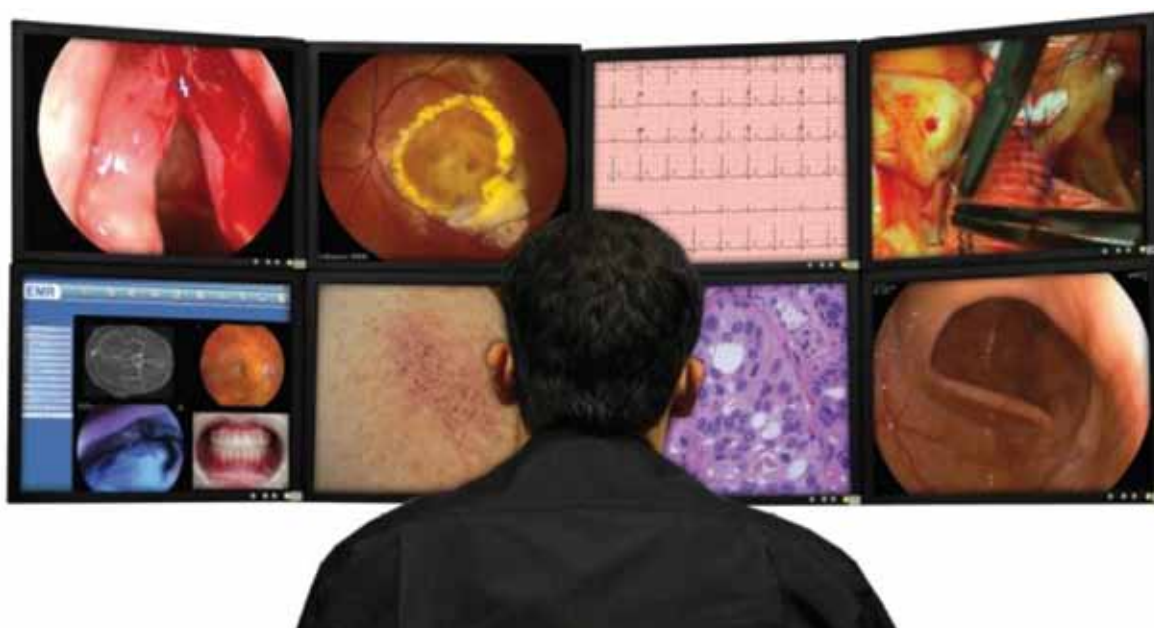
1. Implement VNA within and across care providers for better care coordination
2. Establish clear governance and ownership
3. Mandate the use of a unique patient identifier
4. Clarify privacy and security rules to share images and documents within and across care providers
5. Address data migration challenges

## WHAT IS VENDOR NEUTRAL ARCHIVING (VNA)?

In most cases when regional imaging networks are being established, an existing, heterogeneous Radiology Information System (RIS), Picture Archive and Communication System (PACS) and other medical imaging documentation and archiving system environment exist. Due to the maturity of the imaging informatics industry, the market includes a large number of applications that vary in their abilities to manage data and communicate it to external systems. One of the key values of any Regional Health Imaging projects supported by VNA is centralising the long-term archiving of images, evidence documents and reports.

In this respect, a VNA provides image storage, management, archiving and routing functions for one or more medical imaging documentation and archiving systems. It may also include integration to a clinical viewer offering secure access to standard imaging data from existing workstations anywhere on the network. The viewer is generally considered an external component to the VNA.

The VNA may be compatible with standardised document sharing services. In this case, VNA allows registering information into a regional or national IHE XDS registry.



## VNA VERSUS MEDICAL IMAGING DOCUMENTATION AND ARCHIVING SYSTEM

VNA is not a medical imaging documentation and archiving system. Using standardised communication, VNA can communicate with any medical imaging documentation and archiving system, regardless of the medical imaging vendor. In this sense, VNA is 'vendor neutral'.

### VENDOR NEUTRAL CAN BE DEFINED AS FOLLOWS:

- **Neutrality to 'ologies':** VNA can communicate with systems from different medical imaging departments: radiology, oncology, pathology, dermatology etc.
- **Neutrality to storage technology:** VNA can communicate with different archiving systems, regardless of the underlying technology.
- **Neutrality to access:** VNA is neutral with respect to vendor-specific devices that produce or consume those images (e.g. for display, distribution or analysis).
- **Neutrality to data format:** VNA can manage medical images regardless of their format (e.g. DICOM, non-DICOM, pdf, jpeg etc.)
- **Neutrality to clinical viewer:** VNA does not require a specific diagnostic application. It can bring images to all sorts of clinical viewers, regardless of their initial purpose, vendors or standards architecture.
- **Neutrality to Information Life Cycle Management.** Information lifecycle management (ILM) provides full management of data including retrieval history, tracking of images<sup>20</sup>

VNA provides access to results. It does not manage the reading workflow. VNA is often deployed in a multi-departmental environment within a hospital or across different care providers, therefore regional health projects are a natural setting for VNA. In this respect, VNA may be purchased by a department, a hospital or a group of hospitals providing shared national, regional, local and departmental medical imaging projects. VNA differentiates from an imaging data center (IDC). IDC provides data center with security, disaster recovery and long-term archiving, while VNA will combine the data center functionalities with clinical life cycle management, and neutrality to data formats.

## VNA MARKET DRIVERS

Among the main driving forces for VNA adoption is the willingness to consolidate and share medical images and documents across care providers' boundaries. This is supported by technology enhancement and standardisation.

### 1. DATA SHARING

One of the key values of VNA is to enable local medical imaging documentation and archiving systems to ingest "foreign data" that come from a different domain (such as a different care provider), but relate to the same patient. The sharing can take place either at:

- Cross-speciality level by supporting document sharing of various unstructured and structured content (e.g. HL7 CDA) serving care coordination. A VNA becomes a key component of a health record sharing infrastructure that is increasingly deployed by several regions/countries around the world<sup>21</sup>.
- Cross-enterprise level e.g. within a group of hospitals or a virtual network of hospitals<sup>22</sup>.
- Cross-stakeholder level e.g. within the continuum of care. Freeing images from siloed vendor solutions to support image sharing across hospitals and towards community care providers (collaborative health or virtual health networks).

20. E.g. linking to Master Patient Indices (MPI), or Enterprise Master Patient Indices (EMPI).

21. This includes countries and regions such as Austria, France, Switzerland, USA, Denmark, England, Slovenia, Netherlands, through a series of IHE Profiles revolving around XDS.

22. A network where a number of hospitals have optimised the bidirectional and/or interactive flow

---

The VNA acts as a data repository and allows authorised users to query and retrieve data into their own work environment.

## 2. CARE PROVIDER CONSOLIDATION

Today, most images and documents are created and managed in different departments. Moreover, most enterprise-wide medical imaging documentation and archiving systems are not compatible with images from other vendors. Fragmentation is therefore significant and exists both at the vendor level and across care provider networks. When hospitals and imaging centres consolidate, disparate systems from different departments and care providers are absorbed. VNA offers a tailored solution to this fragmentation, by maintaining the diagnostic applications within the care provider while sharing the same data repository.

## 3. LIFECYCLE MANAGEMENT

Data files grow exponentially both in size and volume. In addition, there is an increasing demand for keeping relevant data for longer periods. VNA solutions help support the data lifecycle management and support cost-efficient retention policies.

## 4. DATA STORAGE AND RELATED COSTS

Storage requirements for imaging are growing much faster than the cost of storage is declining. Moreover, most hospitals operate multiple image and documents archive silos, mostly from different vendors with different databases and database managers, along with different hardware configurations, workflow requirements and service contracts. In this heterogeneous environment, care providers require high-performance access to large image files within a cost-effective and scalable storage infrastructure. VNA offers a solution storing images and documents centrally and saving money on multiple departmental storage archives.

## 5. DATA MIGRATION

VNA allow users to -among others- avoid complex, expensive and time-consuming data migration in the future (e.g. in case of system replacement).

## 6. QUALITY OF CARE

VNA is an essential building block providing access to medical images and documents for Electronic Patient Records at hospital level, and to Electronic Patient Record at regional level. This enables seamless care delivery and knowledge sharing, responding to the demand for improved quality of care<sup>23</sup>.

# MARKET MATURITY, SOPHISTICATION LEVEL AND DELIVERY MODEL

## 1. MARKET MATURITY

The implementation of VNA requires the following key elements: the readiness and willingness to cooperate and share images and clinical data among departments and with other healthcare providers, as well as a high level of IT penetration.

The market maturity is therefore dependant on a number of variables, which COCIR summarises as follows:

1. Need for document/image management
2. IT maturity, with a focus on cost optimisation
3. Heterogeneity of the IT ecosystem
4. Demand for structured data recovery processes across the hospital data repositories
5. Willingness to share

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23. See point 1. Sharing

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Cost is not the only factor driving care providers to implement VNA. The need to share information and structured data management is the main driver for VNA implementation.

## 2. LEVEL OF SOPHISTICATION

**COCIR's VNA definition is currently focused on sophistication level for archiving, and depicts the following four levels:**

- **Level 1:** Archiving at the departmental level with DICOM only and PACS independent
- **Level 2:** Archiving enterprise wide with multi-PACS and DICOM only
- **Level 3:** Archiving enterprise wide and -ologies neutral (multi-specialty), neutrality to data format (DICOM, non DICOM images such as pdf, jpeg, and clinical structured documents increasingly standardised based on HL7 CDA).
- **Level 4:** Archiving cross-enterprise or at regional level, neutrality to data format (DICOM and non DICOM, such as pdf, jpeg, and clinical structured documents increasingly standardised across Europe on HL7 CDA).

## 3. DELIVERY MODELS

**Different delivery models co-exist based on the owner of the VNA:**

- **Hosted.** The VNA vendor or third party IT provider owns and manages the entire hardware, software and storage infrastructure associated with a VNA, in a location remote from the care provider. Often called the 'Cloud' model.
- **Non-hosted.** Care providers own and manage the entire hardware, software, and storage infrastructure associated with a VNA.
- **Hybrid.** The VNA delivery model offers a mix between hosted and non-hosted. For example, the VNA vendor or third party IT provider might own and manage the entire hardware, software and storage infrastructure associated with a VNA, but on the care provider's site.

In terms of governance and ownership, each market has developed its own model. A variety of approaches co-exist, most often driven by financial and funding mechanisms, either centrally funded by government (e.g. NIMIS<sup>24</sup> project in Ireland aims to improve healthcare by implementing a centralised VNA) or locally by the care providers (e.g. UK Trusts collaborate to realise economies of scale).

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24. Ireland's National Integrated Medical Imaging System  
<https://healthmanagement.org/c/imaging/issuearticle/ireland-s-national-pacs-project>



## MARKET SIZE AND GROWTH: VNA MEDICAL IMAGING MARKET IN EUROPE AND BEYOND

The VNA space in medical imaging is expected to grow over the coming years. Today, the USA and overall North America are by far the most advanced market for VNA.

COCIR estimates the VNA market in Europe is currently representing €42m and will grow to €81m by 2017.

Figure 1: VNA medical imaging market in Europe and Beyond

	RADIOLOGY IT MARKET				VNA			
	2013		2017		2013		2017	
COUNTRY	Imaging IT Market Estimate 2013	CAGR 2013-2017	COCIR Market Coverage	Market Estimate 2017	Total VNA market (=sales incl. Services)	% of VNA market against total Imaging IT market 2013	Total VNA market (=sales incl. Services)	% of VNA market against total Imaging IT market 2017
<b>IN MILLION €</b>								
<b>GERMANY</b>	100	0%	65%	100	5	5%	10	10%
<b>FRANCE</b>	52	5%	60%	55	8	15%	15	27%
<b>UK</b>	140	-3%	80%	136	12	9%	22	16%
<b>ITALY</b>	83	0%	78%	83	3	4%	6	7%
<b>SPAIN AND PORTUGAL TOTAL</b>	42	0%	80%	42	2.5	6%	6	14%
<b>AUSTRIA</b>	19	1%	85%	19	0.5	3%	2	10%
<b>SWITZERLAND</b>	19	1%	85%	19	1	5%	3	16%
<b>BELGIUM</b>	17	0%	90%	17	2	12%	4	24%
<b>THE NETHERLANDS</b>	30	-2%	95%	29	2.5	8%	5	17%
<b>NORDICS</b>	50	2%	60%	51	5	10%	8	16%
<b>WESTERN EUROPE</b>	552	-3%	75%	535	41	7%	79	15%
<b>EASTERN EUROPE</b>	27	4%	50%	28	1	4%	2	7%
<b>RUSSIA</b>	18	7%	40%	19	0.5	3%	1	5%
<b>TURKEY</b>	10	5%	40%	11	0.5	5%	1	10%
<b>MIDDLE EAST</b>	35	8%	80%	38	5	14%	5	13%

Source: COCIR eHealth Intelligence (2013)

COCIR vendors estimate that the VNA market targeting medical imaging is an integral part of the current medical imaging IT market, cannibalising part of the traditional medical imaging market. Therefore the expected increase in the VNA market does not necessarily mean that the overall medical imaging IT market will significantly increase. On the contrary, COCIR estimates the overall medical imaging IT market to remain flat in Europe.

## COCIR RECOMMENDATIONS

### 1. IMPLEMENT VNA WITHIN AND ACROSS CARE PROVIDERS FOR BETTER CARE COORDINATION

It is not only about medical image and documents archiving. It is about supporting the streamlined and ubiquitous sharing of a patient's longitudinal record across care providers and departments' boundaries. It is of paramount importance for the realisation of patients' rights for cross-border healthcare.

### 2. ESTABLISH CLEAR GOVERNANCE AND OWNERSHIP

The complexity of regional health projects stems from the large number of participating stakeholders and governance complexity. Successful implementation of VNA depends on clear governance and ownership of the project.

### 3. MANDATE THE USE OF A UNIQUE PATIENT IDENTIFIER

While VNAs can help to cross identify patients with local medical record numbers, the use of a country-wide patient identifier reduces the complexity of this solution.

### 4. CLARIFY PRIVACY AND SECURITY RULES TO SHARE IMAGES AND DOCUMENTS WITHIN AND ACROSS CARE PROVIDERS

Current data protection rules might prevent Regional Health Imaging projects and VNA from realising their full potential by limiting the sharing of patients' longitudinal imaging record across different care providers.

### 5. ADDRESS DATA MIGRATION CHALLENGES

One of the key values of the Regional Health Imaging projects and VNA is centralising the long-term archiving of health data (images, evidence documents, and reports). In most cases, images and documents need to be migrated from the existing Radiology Information Systems (RIS), Picture Archiving and Communication Systems (PACS) and medical imaging documentation and archiving systems to the VNA. This implies a significant variation in data management, in particular in a multi-vendor environment. This calls for clear processes and policies to ensure a smooth transition.

# PERSONALISED MEDICINE

HOW eHEALTH CONTRIBUTES

# 3





## **PART 3 PERSONALISED MEDICINE**

# **3**

### **HOW eHEALTH CONTRIBUTES**

<b>WHAT IS PERSONALISED MEDICINE?</b> .....	<b>25</b>
<b>WHAT IS THE VALUE OF PERSONALISED MEDICINE?</b> .....	<b>25</b>
<b>HOW WILL PERSONALISED MEDICINE TRANSFORM HEALTHCARE AND REDUCE COSTS?</b> .....	<b>26</b>
<b>THE CONSEQUENCES OF PERSONALISED MEDICINE ON HEALTHCARE</b> .....	<b>27</b>
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Ensuring that citizens have access to safe, quality treatment lies at the very heart of our European healthcare systems, and Personalised Medicine is an integral part of making this dream a reality.

Personalised Medicine should enable a targeted preventive, diagnostic or therapeutic regime to a patient resulting in a more effective and efficient cure of its specific disease symptoms or avoid the incidence of any disease. Personalised Medicine results in a transition from the current 'one size fits all' approach to a patient centered healthcare. However, this is not as easy it sounds. To reap the full benefits of Personalised Medicine, we need to transform our healthcare systems. A multi-stakeholder collaborative approach is needed, and a series of legal, technical and societal aspects needs to be addressed to progress on the path to Personalised Medicine.

COCIR developed this paper to share the medical technology industry's perspective, in particular with regards to the role of medical imaging and eHealth systems in supporting Personalised Medicine.

This paper provides a definition of Personalised Medicine. It describes the benefits for healthcare systems and patients, as well as the impact on other sectors of healthcare.

Last but not least, the paper provides recommendations to accelerate the journey towards widespread use of Personalised Medicine.

*Personalised Medicine is the right course of actions to the right patient at the right time.  
It involves prevention, diagnosis, treatment and follow up.*

### **COCIR RECOMMENDATIONS**

COCIR encourages policymakers and stakeholders to work together to provide the right conditions for the development of Personalised Medicine:

- 1.** Digitise patient records and drive interoperability to ease access to clinical data
- 2.** Drive Personalised Medicine at European level, including clinical decision support systems
- 3.** Invest in robust networked IT infrastructures
- 4.** Continue efforts to promote open and standardised data
- 5.** Strengthen IT skills in the healthcare ecosystem
- 6.** Adopt a regulatory framework that allows access to health data with proportionate safeguards



## WHAT IS PERSONALISED MEDICINE<sup>25</sup> ?

Personalised Medicine is an evolution from today's medical model of standardised clinical pathways and drugs licensed for an entire population towards an approach which recognises the differences between individuals in their health risks, and their responsiveness to treatments. We have already embarked on this journey with Stratified Medicine, which attempts to cluster populations into smaller groups, based on their phenotypic characteristics. As more detailed knowledge becomes available, including genomic and proteomic data, we now need to consider how to evolve and adapt preventive, diagnostic, therapeutic and follow-up actions to each individual person. In addition, the adaptation needs to take into account clinical information, the individual's specific epidemiologic and social context, personal preferences and lifestyle, etc. Over time, as accuracy and confidence levels increase, we will move closer to the goal of Precision Medicine, completely customising the care to the individual, to optimise outcomes or prevent the incidence of any disease.

In COCIR's view, although -omic information and corresponding research are very important, Personalised Medicine goes beyond using genomic information for personalising treatment. Personalised Medicine must be seen in the context of a holistic approach to healthcare, in which the patient becomes the central stakeholder.

*Personalised Medicine can be defined by the four Ps:  
**p**redictive, **p**reventive, **p**articipative and **p**recise.*

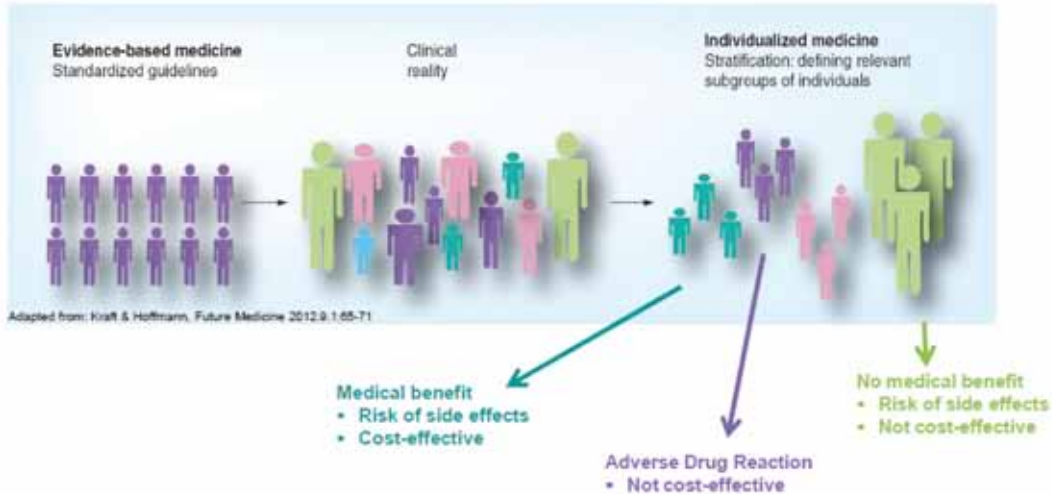
## WHAT IS THE VALUE OF PERSONALISED MEDICINE?

Commonly accepted benefits of Personalised Medicine include:

- Focus on prevention and prediction of disease rather than reaction to it
- Detection of diseases at an earlier stage, when it is easier and less expensive to treat effectively
- Ability to make more informed medical decisions
- Better-targeted therapies allowing higher probability of desired outcomes
- Reduced probability of adverse reactions to medicines
- Reduced time, cost and failure of clinical trials for new therapies
- Improved healthcare cost containment

25. The European Commission defines Personalised Medicine as a medical model using molecular profiling for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to diseases and/or to deliver timely and targeted prevention. Commission Staff Working Document - Use of '-omics' technologies in the development of Personalised Medicine – 25 October 2013  
[http://ec.europa.eu/health/files/latest\\_news/2013-10\\_personalised\\_medicine\\_en.pdf](http://ec.europa.eu/health/files/latest_news/2013-10_personalised_medicine_en.pdf)

*The promise of Personalised Medicine: from one size fits all to patient centered care models*



## HOW WILL PERSONALISED MEDICINE TRANSFORM HEALTHCARE? THE IMPACT ON HEALTHCARE STAKEHOLDERS

All stakeholders in the healthcare ecosystem are impacted by Personalised Medicine:

**The patient** will have specific and highly efficient preventive schemes, keeping him or her healthy (primary prevention), or preventing a disease from becoming critical (secondary prevention). The patient will need fewer, but more relevant, diagnostic tests and interventions will become more effective with fewer side effects.

*Personalised Medicine starts with the patient.*

**Authorities and payers** in general will profit from lower cost healthcare with better outcomes. This will truly materialise when healthcare reimbursement is based on value with a move from fee-for-service to fee-for-outcome. Personalised Medicine has created great expectations in terms of increasing quality and decreasing cost. The ability to accurately predict which cohorts or individuals will respond to specific treatments will permit more targeted interventions, and more effective care pathways. Those who are unlikely to benefit from treatments can avoid unnecessary diagnostics tests and the risks associated with the side effects of drugs.

**Pharmaceutical companies**, working with a 'value-based' economy, as well as **healthcare-related industries** such as imaging equipment and ICT companies, will face a more differentiated palette of innovation challenges which change the attractiveness of existing versus novel strategies. Existing broad spectrum drugs, diagnosis methods and treatments seen today to be effective may over time become replaced, for all patient groups for which more targeted alternatives prove to be even more efficient and effective.

Personalised Medicine will also impact the **healthcare professional**. Probably the biggest change will be the switch from a provider-centered approach to a patient-centered approach. When the patient is in the middle of the process healthcare becomes

de facto an interdisciplinary activity with much more communication between all stakeholders, even crossing the boundaries of the care providers, such as hospitals, family doctor practices, home care organisations and other institutions. The different activities in a care trajectory will be driven by scientific evidence coming from research and analysis of clinical data. This may be perceived by clinicians as limiting their freedom, but in the end, it will enable them to deliver better results. In a value-based or 'fee for outcome' context this will be beneficial for them as well.

## THE CONSEQUENCES OF PERSONALISED MEDICINE ON HEALTHCARE

Personalised Medicine will have significant consequences at many levels.

### CONNECTING GENOTYPE WITH PHENOTYPE

Our genotype contains the recipes for the biochemical processes that shape our body and its functioning. However it is the actual realisation, called the phenotype that determines an individual's response to medical diagnosis and treatment. The phenotype of the patient is recorded in the patient record, including images, biomarkers, vital signs and next generation sequencing data. The relation between genotype and phenotype is complex, only partly understood and it depends on many external factors. It is very important to study and understand this relationship much better so this is a prominent area for medical research. By investigating the relation between both, medical science can detect for example that a specific gene (part of the genotype) is correlated with non-response to a specific drug (an expression of the phenotype). With this knowledge, we can choose the right therapy for the right patient. The more data we have to describe the patient's phenotype the more correlation medical science will detect.

### BIG DATA<sup>26</sup>

Science and ICT have evolved to the point where data analysis and smart use of information can enable paradigm shifts in healthcare. Therefore collecting, mastering and analysing data to support evolution towards more efficient and effective healthcare will become very important.

- Analysis of data will increasingly drive the move towards evidence-based medicine, with unwarranted variation in effectiveness of diagnosis and treatment becoming unacceptable to both patients and payers.
- Data will cover the whole spectrum of sources: pathology, imaging data, -omic data, and clinical data<sup>27</sup>.
- Collecting meaningful data requires the identification and unambiguous definition and measurement of relevant biomarkers<sup>28</sup>. Biomarker technology will be one of the cornerstones of Personalised Medicine. Molecular imaging is one emerging domain that promises very sensitive and specific biomarkers.

All this will require combining huge amounts of data. Innovative technologies will be needed to collect, store, aggregate, combine, analyse, and present this (big) data.

### CLINICAL WORKFLOW

Clinical workflow and the supporting tools will also change drastically. Over the past years, reimbursement pressures increasingly lead to standardised practice where healthcare professionals follow clinical pathways with scientifically demonstrated effectiveness and efficiency, "squeezing" similar patients in the same care trajectory. With the advent of Personalised Medicine, the need to follow such evidence-based protocols will increase, but at the same time these prescribed clinical pathways will become more flexible in that they can be adjusted "on the fly" to the insights about the patient phenotype. Therefore, there will be a shift from static upfront-defined pathways to such just-in-time calculation of next steps at the point of care, based on the current and changeable clinical data and formalised medical knowledge. Such dynamic clinical protocols will require sophisticated clinical decision support tools able to make inferences based on the results of clinical trials and retrospective data analysis.

26. See Part 1 on Big Data

27. Archived in Electronic Patient Records

28. Any biological measurable parameter that can be used to identify a physiological condition

## HOW eHEALTH CONTRIBUTES

### eHEALTH TOOLS

Personalised Medicine requires access to all relevant clinical information: sharing patient records will be paramount. Electronic Patient Records need to aggregate data from many different sources, including from hospital, primary care and social context. This will require more focus on technical and semantic interoperability between systems.

The expected growth of the body of knowledge in support of Personalised Medicine and the amounts of data needed to use that knowledge in clinical practice will inevitably create a strong demand for more sophisticated tools for clinicians to support their reasoning and actions. Clinical decision support tools will be essential to support clinical workflow (see above) and interpretation of data. This is a novel domain and much development needs to be done at the scientific, technical and practical level to develop these tools and turn them into practical aids in daily clinical practice.

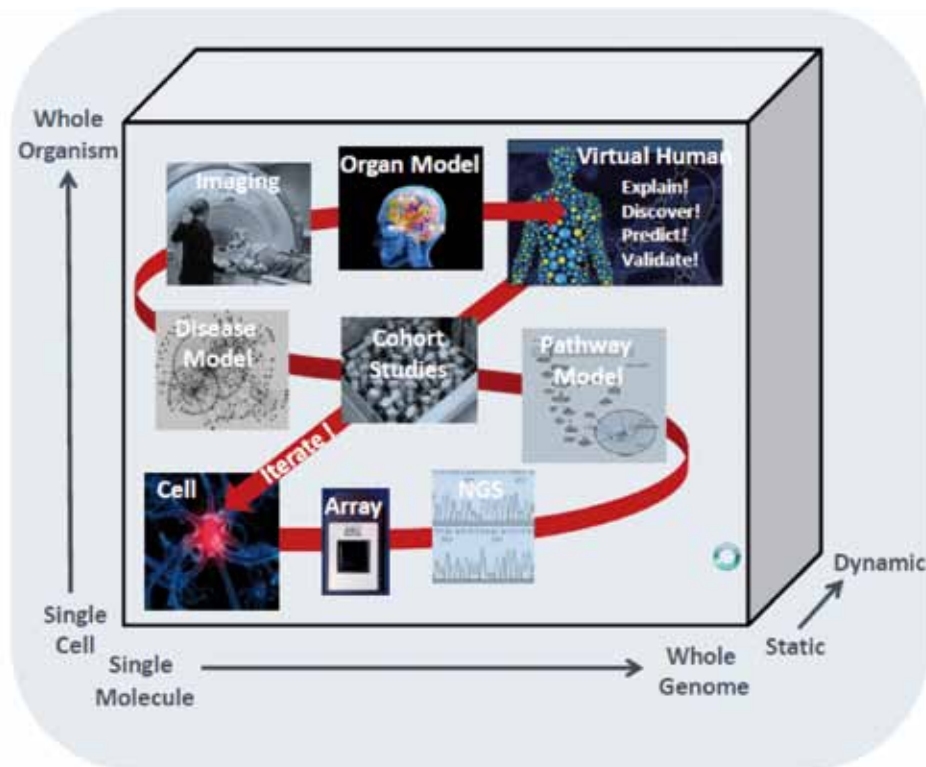
Analysis of large amounts of data becoming so paramount, under the complex restrictions of privacy, security and safety regulations, it is clear that there are tremendous challenges ahead to create the ICT infrastructure to support the developments described in this paper.

*Clinical Decision Support Systems help care providers combine patient data with evidence based knowledge to support better outcomes.*

### MEDICAL IMAGING

Progress in imaging devices, image processing (e.g. radiogenomics) are very relevant to Personalised Medicine. Although current technologies can already deliver Personalised Medicine, more research and development is needed at all levels.

Figure 2: Medical imaging's role in understanding evolution of disease





## COCIR RECOMMENDATIONS

### 1. DIGITISE PATIENT RECORDS AND DRIVE INTEROPERABILITY TO EASE ACCESS TO CLINICAL DATA

Personalised Medicine requires access to and integration of clinical data. Care providers must continue to invest in deploying Electronic Patient Record systems, to capture and store clinical data in an efficient, standardised and cost-effective manner, whilst protecting individual privacy. Additionally, all care providers, involved in taking care of a patient must team up to enable integration and access to all patient relevant data.

### 2. DRIVE PERSONALISED MEDICINE AT EUROPEAN LEVEL

COCIR calls on the EU to drive the development and adoption of Personalised Medicine. Europe needs a comprehensive work plan for 2014-2018 to address barriers and drivers. Key elements of the strategy should be:

- Closer collaboration between industry and academia, and between pharmaceutical and diagnostics manufacturers.
- Better recognition and research funding for the tools of Personalised Medicine, including medical imaging and the emerging field of radiogenomics, and more sophisticated Clinical Decision Support systems at the point of care.
- More screenings or diagnostic tests: to deliver the full potential of Personalised Medicine, much more use will be required of predictive tests, biomarkers, imaging and other diagnostics.

### 3. INVEST IN ROBUST NETWORKED IT INFRASTRUCTURES

Investments in robust IT infrastructure, technological upgrades, structural changes and technical interoperability are needed to provide a sound basis for collecting, processing, and analysing data from disparate sources. These investments are needed at all levels: care providers, health authorities, research and academics.

### 4. CONTINUE EFFORTS TO PROMOTE OPEN AND STANDARDISED DATA

- Share results of clinical trials in a transparent and exploitable format
- Promote the adoption of international consensus data standards
- Invest in interoperability between health data, -omics and imaging databases

### 5. STRENGTHEN IT SKILLS IN THE HEALTHCARE ECOSYSTEM

With Personalised Medicine, healthcare professionals will be asked to move beyond traditional reactive medicine towards proactive healthcare management, employing innovative technologies (e.g. testing and screening, companion diagnostics etc) to prevent and treat disease in new ways. This calls for training a new multidisciplinary generation of general practitioners, specialists, health data scientists and researchers able to use data analytics, bio-informatics, mathematical modelling, statistics etc.

- Introduce IT disciplines in medical curricula and train healthcare and research professionals
- In addition, new types of professionals able to deal with data will have to join the public health services to ensure usability and interoperability of the information stored

### 6. ADOPT A REGULATORY FRAMEWORK THAT ALLOWS ACCESS TO HEALTH DATA WITH PROPORTIONATE SAFEGUARDS

- Promote a pragmatic, flexible, future-proof legal framework
- Allow the secondary use of data for health purposes, with patient consent
- Allow transfer of data over national borders



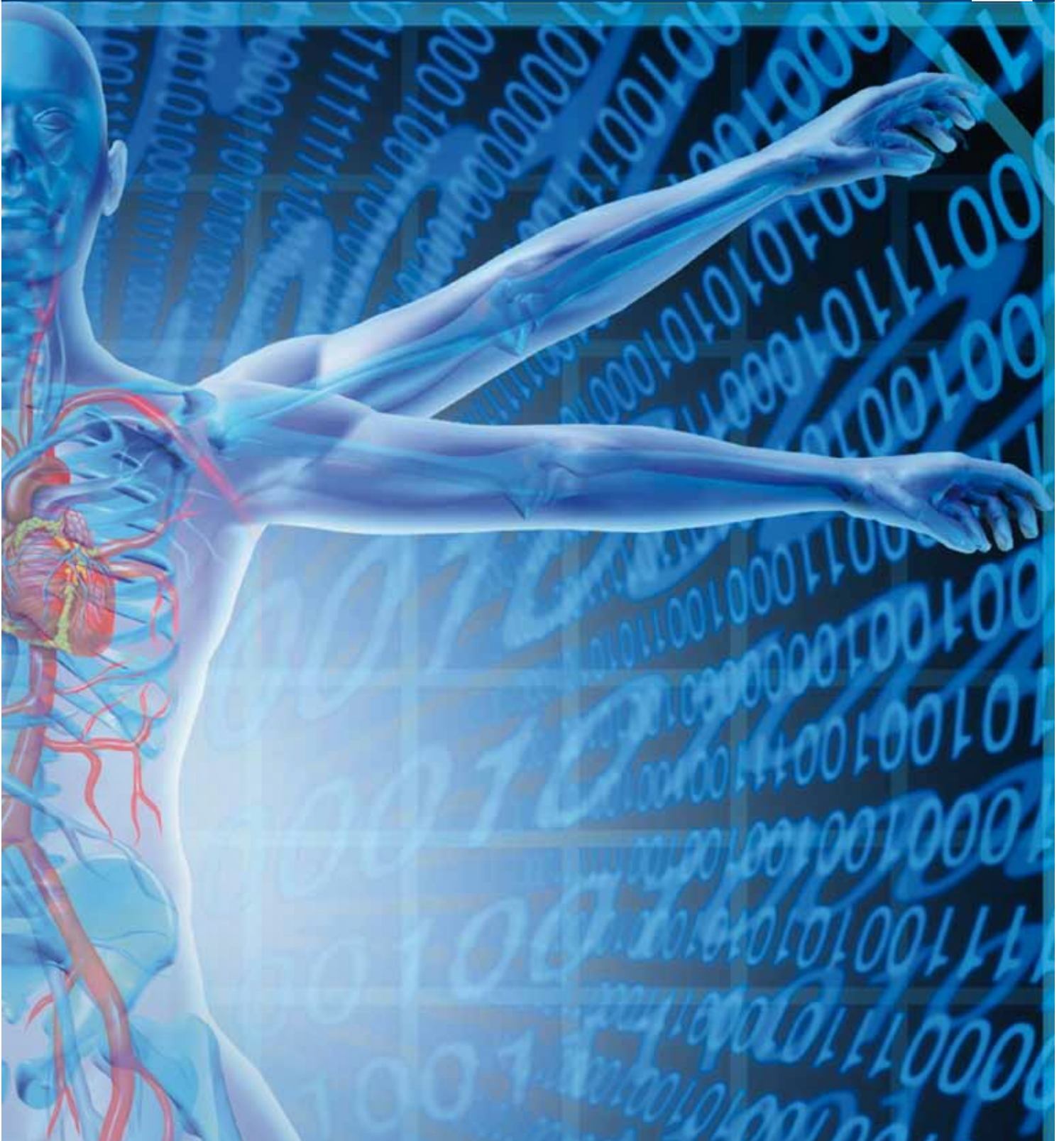
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## NOTES

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# LEGAL AND REGULATORY TRENDS

# 4



## PART 4 LEGAL AND REGULATORY TRENDS

<b>A - REGULATORY TRENDS ON MEDICAL SOFTWARE</b> .....	32
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### A REGULATORY TRENDS ON MEDICAL SOFTWARE

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#### REGULATORY TRENDS ON MEDICAL SOFTWARE

Considering technology is evolving so fast, this requires a regulatory framework commensurate with the high level of innovation and complexity in products and services. The current regulatory system must evolve fast to keep pace with the new needs of healthcare.

Solutions are becoming more complex and more integrated. Increasingly, medical equipment is being controlled by software, almost to the extent that medical devices are software. This requires more specific attention from regulators to software, its development and validation in order to bring more safety, highest quality while increasing access to healthcare in a cost-efficient way.

The explosion of mHealth apps for both consumer and professional use, moreover, shows that many small businesses are part of this new ecosystem alongside more established market players. It is therefore important that regulation does not inhibit the development of new solutions while also protecting the safety and trust of users.

*COCIR calls for a supportive, predictable and cost-efficient regulatory system, to consolidate the EU's leadership position in medical device innovation and maintain patients' rapid access to healthcare.*

#### CURRENT REGULATORY FRAMEWORK FOR MEDICAL SOFTWARE IN EUROPE

Medical devices are regulated through a number of New Approach Directives such as:

- 93/42/EEC, Medical Devices Directive
- 90/385/EEC, Active Implantable Medical Devices Directive
- 98/79/EC, In Vitro Diagnostic Medical Devices Directive

These were transposed into national law in European Member States after their adoption at European level. Through the Directive 2007/47/EC – which amended the Medical Devices Directive and has been enforced since March 2010 at national level in all EU Member States – the definition of 'medical device' was amended to include also software, and text was added to the Annex IX classification criteria, stating that 'standalone' software is to be considered an active medical device.

Due to the unclear status of several forms of software, and because of the non-uniform interpretation in some EU Member States about why certain forms of software are medical devices, the European Commission created a Software Working Group in December 2009. The objective of this Working Group is to establish guidance on how and under what conditions a form of software is a medical device or not.

29. [http://ec.europa.eu/health/medical-devices/documents/guidelines/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm)



This guidance started on the basis of a Swedish draft guideline. This European guidance MEDDEV 2.1/6<sup>29</sup> was published in January 2012 and is entitled “Guidelines on the qualification and classification of standalone software used in healthcare within the regulatory framework of medical devices.” The purpose of this non-binding European guidance document is to clarify the relevant criteria for qualification of standalone software that is a medical device, and the application of classification criteria for such software.

In doing so, the guidance is intended to harmonise the interpretation of the regulatory requirements for standalone software. Since early 2013, this MEDDEV guidance document has been further discussed as the document’s decision tree and definition of the term ‘standalone’ have proven to be problematic for some market players. There is also a general need for additional updates based on fast-evolving technologies. COCIR is actively involved in this revision process, together with its partner association GSMA, as a member of the Commission’s Software Working Group.

On 26 September 2012, the European Commission adopted a Proposal for a Regulation on medical devices and a Proposal for a Regulation on in vitro diagnostic medical devices which will, once adopted, replace the existing three medical devices Directives listed above. This new Regulation is planned to be adopted by approximately 2015-2016. So far, no new specific requirements are foreseen for medical software. However, COCIR is concerned that the European Parliament’s proposal to amend the definition of ‘medical device’ could bring many forms of general-purpose (non-medical) software into the scope of the new Regulation.

Besides this, a lot more can be done to tailor the new Regulation to the unique characteristics and rapid innovations of medical software. The classification rules, for example, are largely unchanged from today’s Directive and were made with hardware in mind. They therefore do not apply well to software, and this has been proven to lead to disparate product classifications and create difficulties at tender level.

In parallel to negotiating the new Regulation, and at the time that this Toolkit went to press, the Commission was in the process of launching a Green Paper on Mobile Health and Wellbeing Applications with the public consultation open until 25 June. This Green Paper will include an analysis of the current regulatory landscape – including legislation on consumer and data protection – and how it applies to mobile apps. Such apps, if they meet the definition of a medical device, are considered to be medical software. However, a great many other health and lifestyle apps are developed and placed on the market every month without an intended medical purpose. The Commission’s Green Paper will consider what need, if any, there might be to address the risks of such apps through existing or future regulation.

Despite the existence of European Union legislation on medical devices and the MEDDEV guidance document mentioned above, **some European countries** have decided to develop specific documents/regulations in order to clarify some aspects of software used in a healthcare setting.

#### **For example:**

##### **SWEDEN:**

The Medical Products Agency published in April 2013 a guideline reflecting many of the questions that they received over the last couple of years. And which is intended to clarify the status of some products that are available on the Swedish market.  
Refer to the Medical Products Agency website<sup>30</sup>

##### **FRANCE:**

Article L.161-38 of the French Code of Social Security was modified on 29 December 2011 by the publication of law no 2011-2012. With this change, the certification of medication prescription software is now in the scope of the Code. The certification requirements, laid out in the June 2012 Certification Standards, are aimed at improving prescription software’s compliance with minimum security and efficiency requirements. Such prescription software is not considered a medical device in France, but is used in a healthcare system in a manner that is integrated with various hardware and software medical devices.  
See the Haute Autorité de Santé website<sup>31</sup>

30. <http://www.lakemedelsverket.se/english/product/Medical-devices/>

31. [http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-06/referentiel\\_certification\\_lap\\_hospitalier\\_juin12.pdf](http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-06/referentiel_certification_lap_hospitalier_juin12.pdf)

**UNITED KINGDOM:** The National Health Service's International Standards Board maintains the national standard ISB 0129 on the application of clinical risk management to the manufacture of health IT systems. Among the requirements of this standard is the need for companies to appoint, to each release of a health IT system, a Clinical Safety Officer responsible for ensuring the safe design of the system by applying a clinical risk management process. Section 2.3 of the standard specified that this Clinical Safety Officer must be a clinician who is qualified and experienced in risk management as applied to health IT systems. Guidance on the implementation of this standard is available at the Health and Social Care Information Centre website<sup>32</sup>

*COCIR welcomes the European Commission's upcoming initiatives, including the expected impending consultation on its Green Paper, to clarify the regulatory environment for medical software and in particular mobile apps. The Commission's guidance should be clear and simple in order to facilitate compliance, fair competition and rapid adoption of new technologies.*

## UPDATES ON REGULATORY STATUS FOR MEDICAL SOFTWARE OUTSIDE EUROPE

Several other geographies have started some regulatory initiatives.

**CANADA** Canada explicitly recognizes that software can be a medical device (refer to [http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md\\_notice\\_software\\_im\\_avis\\_logicels-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_software_im_avis_logicels-eng.php)). Canada has released and is enforcing its new guidance document. It clearly indicates that they consider it possible for software to be a medical device.

### **It classifies these devices based on their classification rules:**

- Class II Software required a license by September 2011 and Class I software by February 2011
- Any patient management software used only for storing, acquiring, transferring or viewing data, or images is considered a Class I medical device
- Any patient management software with capabilities beyond basic data visualization, acquisition, transfer and storage is considered a Class II medical device:
- Includes any patient management software involved in data manipulation, data analysis, data editing, image generation, determination of measurements, graphing, flagging of results, identifying a region of interest or performing calculations (if the software performing calculations directly impacts the diagnosis and/or treatment of a patient)
- Free and Open-Source Software (FOSS) that is used for patient management is subject to the same regulatory requirements

For more information, see Health Canada's dedicated page of Frequently Asked Questions about 'Software Regulated as a Medical Device'<sup>33</sup>

**JAPAN** Japan's Pharmaceutical Affairs Law (J-PAL) was revised in 2013 and will be enforced from November 2014 onwards. Before that time, ordinances will be adopted on the various aspects of the J-PAL that have changed. Whereas the old law only regulated software in combination with medical device hardware, the revised J-PAL also regulates Standalone Medical Device Software (SMDS). SMDS includes, for example, CT image processing software for diagnostic purposes will need approval under the revised J-PAL even if this software runs off of a general purpose computing platform.

32. <http://www.isb.nhs.uk/documents/isb-0129/amd-39-2012/01291305guidancev2-1.pdf>

33. [http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md\\_qa\\_software\\_im\\_qr\\_logicels-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_qa_software_im_qr_logicels-eng.php)

## THE USA US FDA considers Mobile Medical Applications as being potentially in the scope of medical device regulation.

In September 2013, the FDA published guidance on 'mobile medical apps', i.e., software running on mobile platforms that meets the definition of 'medical device' and is intended to either be used as an accessory to a medical device or to transform a mobile platform into a medical device. The guidance recognises that many mobile apps may not meet the definition of medical device. Moreover, while some mobile apps may meet the definition of 'medical device,' they may pose a lower risk to the public. FDA therefore states in the introduction of the guidance that it "intends to exercise enforcement discretion over these devices (meaning it will not enforce requirements under the [Food, Drug and Cosmetic] Act)."

The guidance can be consulted at the FDA dedicated page<sup>34</sup>.

## INITIATIVE RECENTLY TAKEN AT INTERNATIONAL LEVEL

The International Medical Device Regulators Forum (IMDRF) validated at their Management Committee meetings of March 2013, a new Work Item on Software as a Medical Device (SaMD), proposed initially by DITTA (The Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association) in 2012.

COCIR considers this is an important step forward in order to achieve a global regulatory convergence on medical software by determining:

- 1) Common key criteria to qualify whether software is a medical device or not
- 2) A risk stratification framework for generic types of SaMD based on their unique risks
- 3) Recommended corresponding controls for the different SaMD types, e.g. development lifecycle requirements, quality management systems, labelling and clinical data

Alignment on these points and their uptake by all IMDRF jurisdictions offers industry an excellent opportunity to achieve future regulation of medical software that is not only aligned but also tailored to software's unique characteristics.

## INTERNATIONAL STANDARDS DEVELOPMENT FOR MEDICAL SOFTWARE TO SUPPORT REGULATORY FRAMEWORK

International Standardisation Organisations such as ISO and IEC have generated international standards which are currently being revised in order to bring some support to the regulatory framework. We have seen an intensification of cooperation between ISO TC 210, ISO TC 215 and IEC TC 62 in order to bring some consistency in international standards covering medical software.

Currently, the IEC 82304-1 and IEC 62304 standards are being revised. In addition, IEC 80001 series covering hospital networks are also progressing.

In addition, standards, profiles and specifications allow a common definition of data and data exchange formats that is essential to enable interoperability at the technical, semantic and organisational levels. As widely recognised standards (e.g. HL7 and SNOMED CT) and profiles (e.g. IHE and Continua) continue to grow geographically, a broader network of consistent communications can enable integrated healthcare delivery while the need for regulation is reduced or where standards can play an important complementary role to the existing regulatory framework.

*COCIR welcomes the implementation of international standards and profiles. Market-driven standards – or the use of existing standards – should be supported while avoiding strict technology mandates.*

34. <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf>

## PART 4 LEGAL AND REGULATORY TRENDS

### B DATA PROTECTION: SAFEGUARDING PRIVACY WHILE ENCOURAGING MEDICAL INNOVATION

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COCIR supports an effective, clear and workable data protection framework and welcomes the European Institutions' efforts to strengthen data protection while allowing the free flow of personal data in the EU.

Access to health data is of paramount importance for delivering seamless and quality healthcare. Medical devices, eHealth systems and networks support the timely and secure flow of patients' data to ensure they are available at the point of care and throughout the healthcare cycle.

COCIR members are concerned that certain provisions in the Commission proposal<sup>35</sup> on the Protection of Personal Data and in the European Parliament LIBE report<sup>36</sup> might restrict the sharing of health data, delay innovation, create legal uncertainty and increase compliance costs. COCIR developed this paper to raise awareness about the special 'data needs' of the healthcare sector: why are health data collected? How are they processed? And how can health data support quality healthcare, medical innovation and research?

The last chapter articulates nine recommendations to find the right balance between protecting privacy and supporting medical innovation.

#### COCIR RECOMMENDATIONS

In order to achieve a single, clear and workable data protection regime that protects privacy and supports healthcare and innovation, COCIR recommends the following:

1. Provide for a harmonised set of rules across the European Union
2. Allow and support the sharing of health data for health and research purposes
3. Enable the secondary use of data for health and research purposes
4. Ensure only data related to a data subject are subject to the Regulation
5. Maintain clear and separate responsibilities between the healthcare provider and the medical technology provider
6. Simplify the conditions for sub-contracting between the healthcare provider and the medical technology provider
7. Avoid unnecessary administrative burden linked to impact assessment obligations
8. Clarify the exemption to the right to be forgotten for 'health purposes'
9. Enable citizens' access to their health data

35. Proposal for a Regulation on the protection of individuals with regards to the processing of personal data and on the free movement of such data (General Data Protection Regulation) [http://ec.europa.eu/justice/data-protection/document/review2012/com\\_2012\\_11\\_en.pdf](http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf)

36. Report on the proposal for a regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0402+0+DOC+XML+V0//EN&language=en>



## BENEFITS OF DATA DRIVEN HEALTHCARE

COCIR members develop many technologies that support the safe, fast and seamless transfer of medical data to support quality healthcare. Diagnostic imaging, biomarkers, Electronic Patient Records, telemedicine, data storage and management, and clinical research tools and processes are critical to the development of state of the art prevention, diagnosis, and treatment and rehabilitation practices as a component of sustainable healthcare. COCIR members also develop and supply data collection and management systems used in the analysis of hospital and healthcare system productivity and efficiency in areas such as patient flow and planning, technology utilisation, optimisation of facilities etc.

Data collected, stored and managed by COCIR members' technologies is also a critical component in driving and informing Life Sciences and healthcare research in Europe. COCIR knows that quality healthcare and medical research depend on the availability of comprehensive health data, collected at the point of care and throughout the healthcare cycle. COCIR urges EU policymakers to carefully consider the whole new range of possibilities to improve citizens' health and healthcare systems through the use of modern data-driven approaches. The latter include telemonitoring, large disease databases, Personalised Medicine, medical imaging, human genome decoding, disease prediction, biobanks, biomarkers and many more. These revolutionary innovations rely on the collection, analysis and sharing of health data to better understand diseases and treat them as part of an efficient and effective healthcare delivery system.

The medical innovations described above are supported by data analysis techniques and tools: Big Data, data analytics, cloud computing, open data and data mining. These processes increase human capacity to understand the data available. Understanding health data means understanding the human body, understanding diseases, understanding our healthcare systems and making the right choices for medical treatment.

## PROTECTING DATA, RESPECTING PRIVACY

Data processing techniques and practices developed above may incur risks to privacy by accelerating and multiplying data flows. These risks should be understood and evaluated in light of the advances of healthcare innovation and benefits to society. Data processing is too often associated with privacy intrusion. A modern and knowledge-based society like the EU should not hinder the progress of health and medical research on the fear that it might increase risks to privacy. Protecting individuals' privacy is critical but unwarranted fears over the use of aggregated and properly protected data should not compromise the uptake of innovations that will benefit patients and society. Privacy protection and innovation should go hand in hand.

New data processing techniques and tools are available to protect privacy through using the right security modules and the right data protection policies. Indeed, using such systems, COCIR contends, would increase levels of privacy protection in some areas where data is currently stored on paper or in unprotected formats. The medical technology industry has invested in robust data security systems and established comprehensive controls to protect sensitive data from intrusion, theft, loss and misuse.

## STRIKING THE RIGHT BALANCE

Society needs to find the right balance between safeguarding privacy and encouraging healthcare innovation. We will not find this balance by accepting fear. On the contrary, we should understand these new opportunities and frame them with adequate and workable safeguards. As Commission Vice President Nellie Kroes said: 'Mastering Big Data means mastering privacy'<sup>37</sup>.

The European Union wishes to create a vibrant life sciences and health technology sector in Europe, at the forefront of global innovation and job creation. COCIR supports this and believes Europe has the necessary skills and infrastructure to deliver provided the right policies and laws are in place to support the development of these assets. A clear, simple and workable data protection legal framework can achieve this for Europe. To this end, COCIR has developed ten key recommendations for Europe's policymakers considering the future framework for data protection and privacy in respect to health and life sciences.

37. [http://europa.eu/rapid/press-release\\_SPEECH-13-1059\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-13-1059_en.htm)

## COCIR RECOMMENDATIONS

This list of recommendations is not exhaustive but is limited to those most relevant to the healthcare sector. More general concerns remain.

### 1. PROVIDE FOR A HARMONISED SET OF RULES ACROSS THE EUROPEAN UNION

Provide for a high level of harmonisation so that business does not need to address different rules throughout 28 Member States. This will provide legal clarity and simplicity.

### 2. ALLOW AND SUPPORT THE SHARING OF HEALTH DATA FOR HEALTH AND RESEARCH PURPOSES

Data collected and managed in Member States in compliance with harmonised legislation must be able to be securely transferred, within and across Member States for the purposes of patient care and relevant medical and healthcare research. 'Big Data' promises to help empower better research and better patient care. It needs as much data as possible to do this and international and global databases will be essential in some instances.

### 3. ENABLE THE SECONDARY USE OF DATA FOR HEALTH AND RESEARCH PURPOSES BY ADOPTING A WORKABLE CONSENT REQUIREMENT

Ease the conditions for consent for health and research purposes. This will accommodate the secondary use of data in research. A 'broad consent' seems more workable than a 'specific' or 'purpose explicit' consent. Maintaining Article 83 as proposed by the Commission would suffice.

### 4. ENSURE ONLY DATA RELATED TO A DATA SUBJECT ARE SUBJECT TO THE REGULATION BY ADOPTING A PROPORTIONATE DEFINITION OF PERSONAL DATA

The definition proposed in the European Parliament LIBE report is too broad and includes data that may help to identify or single out a data subject, directly or indirectly. For instance, the serial number of a medical device may be regarded as personal data subject to the Regulation. This will increase the administrative burden for medical device manufacturers without bringing benefits for privacy.

### 5. MAINTAIN CLEAR AND SEPARATE RESPONSIBILITIES BETWEEN THE HEALTHCARE PROVIDER AND THE MEDICAL TECHNOLOGY PROVIDER (DATA PROCESSOR) AS PER THE CURRENT REGIME TO SECURE LEGAL CERTAINTY

The healthcare provider (data controller) should be responsible and liable towards the patient data subject. The medical technology provider (data processor) should be responsible and liable towards the healthcare provider (data controller) by contract. Medical technology providers process personal data based on instructions from the healthcare provider. They do not maintain a direct relationship with the patient and should not be liable to them.

### 6. SIMPLIFY THE CONDITIONS FOR SUB-CONTRACTING BETWEEN THE HEALTHCARE PROVIDER AND THE MEDICAL TECHNOLOGY PROVIDER

The relationship between the healthcare provider (controller) and the medical technology provider (processor) should be established by contract, not by law. Requesting the 'prior permission' of the healthcare provider before sub-listing another processor creates additional burden and might create delays. In healthcare, delays in processing health data may be prejudicial to patient health and safety.

### 7. AVOID UNNECESSARY ADMINISTRATIVE BURDEN LINKED TO IMPACT ASSESSMENT OBLIGATIONS

The Commission proposal and the LIBE report provide prescriptive obligations for carrying out impact assessments. Healthcare organisations should be able to maintain their own assessment, based on their specific type of organisation, legal requirements, contractual obligations, and, where appropriate, internal policies.

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#### **8. CLARIFY THE EXEMPTION TO THE RIGHT TO BE FORGOTTEN FOR 'HEALTH PURPOSES'**

Clarify the exemption to the right for erasure/right to be forgotten for 'health purposes' rather than for 'reasons of public interest in the area of public health' (as currently stated in the Commission and LIBE proposals). We are concerned that the concept 'reasons of public interest in the field of public health' lacks clarity and may not include delivery of care. We therefore suggest using 'for health purposes' to clarify the ambiguity and provide legal clarity.

#### **9. ENABLE CITIZENS' ACCESS TO THEIR HEALTH DATA**

Last but not least, the collection and processing of health data plays a central role in facilitating citizens' interactions with, and access to, the healthcare system. Indeed, the prompt availability and integrated use of health data are not only necessary for the better internal functioning of healthcare systems but ultimately serve the purpose of facilitating citizens' inclusion and empowerment. Citizens cannot be in control of their health if they do not have access to their medical data. More and more, this will involve innovative technologies such as mobile devices and applications. We urge policymakers not to lose sight of this fact in developing a data protection framework that effectively promotes citizens' engagement.

## ANNEX FREQUENTLY ASKED QUESTIONS (FAQ)

### WHY AND HOW ARE HEALTH DATA USED FOR HEALTH PURPOSES?

#### WHY ARE HEALTH DATA USED FOR HEALTH CARE PURPOSES?

Personal data are used by health professionals to diagnose the patient condition, monitor the disease over time and select the best treatment. Personal data may be stored over time in an Electronic Patient Record to keep a record of patients' health history (medication history, vaccination, allergies, family antecedent, surgeries etc). Health professionals include medical doctors, nurses and allied professions, midwives, laboratory technicians. They have a professional obligation to secrecy.

Personal data may also be processed by non-medical staff for administrative purposes (e.g. reimbursement, billing). Non-medical staff can include administrative staff from hospital, general practitioner's office, laboratories etc. These staff members are trained to the sensitivity of health data and have signed a commitment of confidentiality with their employer.

Personal health data contained in Electronic Patient Records are also used by citizens to better communicate with providers, better understand their health and treatment options, and to make sure health information is as accurate and complete as possible. Data from Electronic Patient Records can also be plugged into a growing number of eHealth tools and applications that help patients better manage their own personal health and wellness, often outside of the context of traditional healthcare.

#### WHY ARE HEALTH DATA USED FOR RESEARCH PURPOSES?

Personal data allow researchers to compare different factors, such as lifestyle and the incidence of disease at an individual level. These observational studies have led to breakthroughs such as identifying the association between smoking and lung cancer and informing treatment of infection in unborn babies.

Research using personal data should only take place within a robust ethical governance framework to ensure that an individual's personal data are only used in research when this is proportionate to the potential benefits for society as a whole. Researchers are given access to personal data only under strict confidentiality controls, which have been effective at preventing misuse and harm to data subjects.

#### WHY ARE HEALTH DATA USED FOR THE MAINTENANCE OF MEDICAL DEVICES?

Professionals employed by medical technology manufacturers (technicians, engineers, medical professionals) access health data for technical maintenance and equipment performance evaluation. This is a regulatory obligation under Directive 93/42/EC. They have a professional obligation to secrecy by contract with their employer.

#### WHY ARE HEALTH DATA USED FOR PUBLIC HEALTH AND EPIDEMIOLOGY PURPOSES?

Public authorities use health data to detect and model epidemic waves, evaluate the efficiency of treatments, make correlations between risk factors and the emergence of diseases (e.g. asbestos and cancer), define population at risk of poor health, and articulate informed-based prevention and public health policies.

### HOW ARE HEALTH DATA USED TO DELIVER MEDICAL INNOVATION? EXAMPLES OF LIFE SAVING MEDICAL INNOVATIONS THAT RELY ON DATA PROCESSING:

**BIOBANKS** are repositories that store biological samples for use in research. Biobanks give researchers access to data representing larger numbers of individual people than could be analyzed in previously used systems. Furthermore, samples in biobanks and the data derived from those samples can often be used by multiple researchers for multiple purposes. Biobanks have become a key resource, supporting many types of contemporary research like genomics and personalised medicine.

**BIOMARKERS** are biological parameters that can be used to identify a physiologic condition. They are traceable substances that are introduced into an organism as a means to examine organ function, or indicate a particular disease state or other aspects of health. Used in medical imaging, biomarkers are an essential element of predictive, preventive and Personalised Medicine.



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**ELECTRONIC PATIENT RECORDS** are a central repository of patient data. EPRs are quickly becoming an incomparable tool giving health professionals easy, timely and targeted access to patient data at the point of care. EPRs can also feed larger databases for secondary use (e.g. research) if the data has been de-identified. Citizens' access to their EPRs is one key method of sharing relevant information to help them navigate the healthcare system and make informed decisions about their health.

**GENOME-BASED PREDICTION OF DISEASES** is an emerging science looking into a person's genome to understand the susceptibility of developing a particular disease. For instance, common diseases such as Type 2 diabetes and coronary heart disease result from a complex interplay of genetic and environmental factors. Recent developments in genomics research have led to the discovery of susceptibility genes for these diseases and opened new opportunities for genetic profiling for personalising medicine.

**LARGE DISEASES DATABASES** are crucial tools to increase knowledge on diseases by pooling data for fundamental, clinical and epidemiological research, and real-life post-marketing observational studies and allow the translation of research into therapeutic solutions. The larger the database the better: studies with large numbers of patients ensure comparability and repeatability of findings, which are cornerstones of scientific work in modern medicine. Patient registries are particularly important for rare diseases, where little data is available. The use of clinical registries is already required by national legislation and with the growing use of Electronic Patient record, the future ability of countries to introduce large-scale, population-level data analysis for medical and health trends will increase. For instance, England is considering creating a nation-wide database containing records of all patients in England (care.data).

**MEDICAL IMAGING** is the technique and process used to create images of the human body to reveal, diagnose, or examine a disease. Medical imaging is critical for early diagnosis and better evaluation of the treatment effect for improved outcomes. Medical Imaging has become a cornerstone of modern medicine in many disciplines: oncology; traumatology, musculoskeletal disorders etc.

**PERSONALISED MEDICINES** are medicines which are tailored to the patient, by opposition to conventional 'one size fits all' drugs (e.g. antibiotics). Personalised Medicines use molecular profiling for determining the predisposition of an individual to disease, for tailoring the right therapeutic strategy for the right person at the right time, and for delivering timely and targeted prevention. Personalised Medicine can improve prevention; improve treatment efficiency and improve patient quality of life.

**TELEMEDICINE** refers to the delivery of healthcare services remotely with the support of ICTs. Telemedicine cuts unnecessary patient travel, best utilises limited professional resources and drives efficiencies in healthcare delivery. Telemedicine relies on the exchange of patient data, including transfer of relevant data outside of the country of origin.

## HOW CAN LARGE VOLUMES OF HEALTH DATA BE BEST EXPLOITED? EXAMPLES OF TECHNIQUES AND TOOLS TO MAKE SENSE OF DATA

**BIG DATA** refers to the increasing volume of data available in different forms, from different origins, collected for different purposes but which can be pooled and analysed for a common purpose. In healthcare, 'Big Data' management systems offer great potential to drive clinical actions and outcomes from analysis of aggregated health, lifestyle, environmental, social, genetic and other factors. The larger the databases, the better the outcomes and in many cases, particularly when dealing with rare and uncommon diseases, this requires sharing and transferring data across regional, national and international borders.

**CLOUD COMPUTING** refers to internet-based computing, where shared servers provide computing power, storage, development platforms or software to computers and other devices on demand. In healthcare, this means that patient data might be stored and processed in a virtual location (the Cloud) as opposed on hospitals and/or research centres' servers. In healthcare, cloud computing is increasingly recognised as the ideal back-end service to manage applications and enable collaboration.

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**DATA ANALYTICS** refers to the discovery and communication of meaningful patterns in data, in order to make sense of the 'Big Data'. Data analytics techniques analyse datasets to describe, predict, and improve performance. Commonly applied in business, data analytics are increasingly used in healthcare.

**OPEN DATA** is data that can be freely used, shared and built-on by anyone – in both the public and private sectors – for any legal purpose. In healthcare, data that is machine-readable, downloadable and accessible via application programming interfaces, while rigorously protecting privacy and confidentiality – including clinical care provider quality information, health service provider directories, databases of the latest medical and scientific knowledge, consumer product data, community health performance information, government spending data and much more – has spawned a vast array of private-sector innovations that have created large-scale public benefit and economic value.

## WHAT ARE THE EXISTING TOOLS AND PRACTICES TO PROTECT HEALTH DATA?

### ANONYMISATION

Anonymisation is the process used to strip personal data from all elements likely to help identify directly or indirectly the data subject (e.g. name, age, address, social security number etc.) These elements are deleted to ensure re-identification is not possible.

### PSEUDONYMISATION

Pseudonymisation is the process of disguising identities - the aim of such a process is to be able to collect additional data relating to the same individual without having to know their identity. This is particularly relevant in the context of research and statistics. Disguising identities can also be done in a way that no re-identification is possible, e.g. by one-way cryptography, which creates in general anonymised data.

### ENCRYPTION

Encryption is the process of encoding messages or information in such a way that only authorised parties can read it. Encryption does not prevent hacking but it reduces the likelihood that the hacker will be able to read the data that is encrypted.

## WHAT TYPE OF PRACTICES WOULD BE RULED OUT BY THE LIBE REPORT IF ADOPTED, OR BY DISPROPORTIONATE DATA PROTECTION RULES?

1. The **NHS IN ENGLAND** is planning to establish a nationwide patient database including all Electronic Patient Records to be accessed by researchers and drug firms (unless patients opt out). The objective is to advance medical science by helping the medical community understand the causes of disease, spot side-effects to new drugs and detect outbreaks of infectious diseases. The Commission proposal and the European Parliament LIBE report would not allow such a system - because it requires that individuals give explicit consent, knowing the specific purpose for which data is being used.
2. **EUROPEAN MEDICAL INFORMATION FRAMEWORK (EMIF)** is a €56 million collaboration to link together existing health data from 40 million European citizens across seven EU countries. EMIF will make health data from a range of sources - including hospital databases, cohorts and national registries - accessible to researchers for studies on obesity and Alzheimer's disease. The development and use of this powerful research resource would be seriously threatened if the LIBE report is adopted because the exemption from specific consent is very narrow.

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### 3. MEDICAL IMAGE PROCESSING SOFTWARE needs to be proven safe and effective before it can be placed on the market.

The development and testing of such software requires actual patient data. Today hospitals can de-identify, or strip their medical images from all identifiers (e.g. patient name, address, social security number etc.) before providing the images to manufacturers for development and testing purposes. Most national privacy laws consider that a medical image stripped from identifiable data is anonymous; therefore no patient consent is needed to use the image for research, development and testing purposes. However six European countries believe that it is not anonymised because the clinician can recognise the image and link it to their patient. As such, according to the law of those six countries medical images can never be called 'anonymous' and therefore always require patient consent. This implies a significant cost for manufacturers. Industry estimates a 25% cost increase:

- The cost of collecting the patient consent is estimated at €100 per image.
- A new software algorithm may require thousands of images to develop and test.
- Minor software updates are tested on about a hundred images. Often there are several releases per year of a particular application.

Introducing a consent requirement will increase the development cost of medical image processing softwares and slow it down, with no benefit to privacy.



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**NOTES**

A large area of the page is filled with horizontal dotted lines, providing a template for handwritten notes.



# COCIR GLOSSARY OF TERMS

# 5



# PART 5 COCIR GLOSSARY OF TERMS

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## PART 1: eHEALTH DEFINITIONS

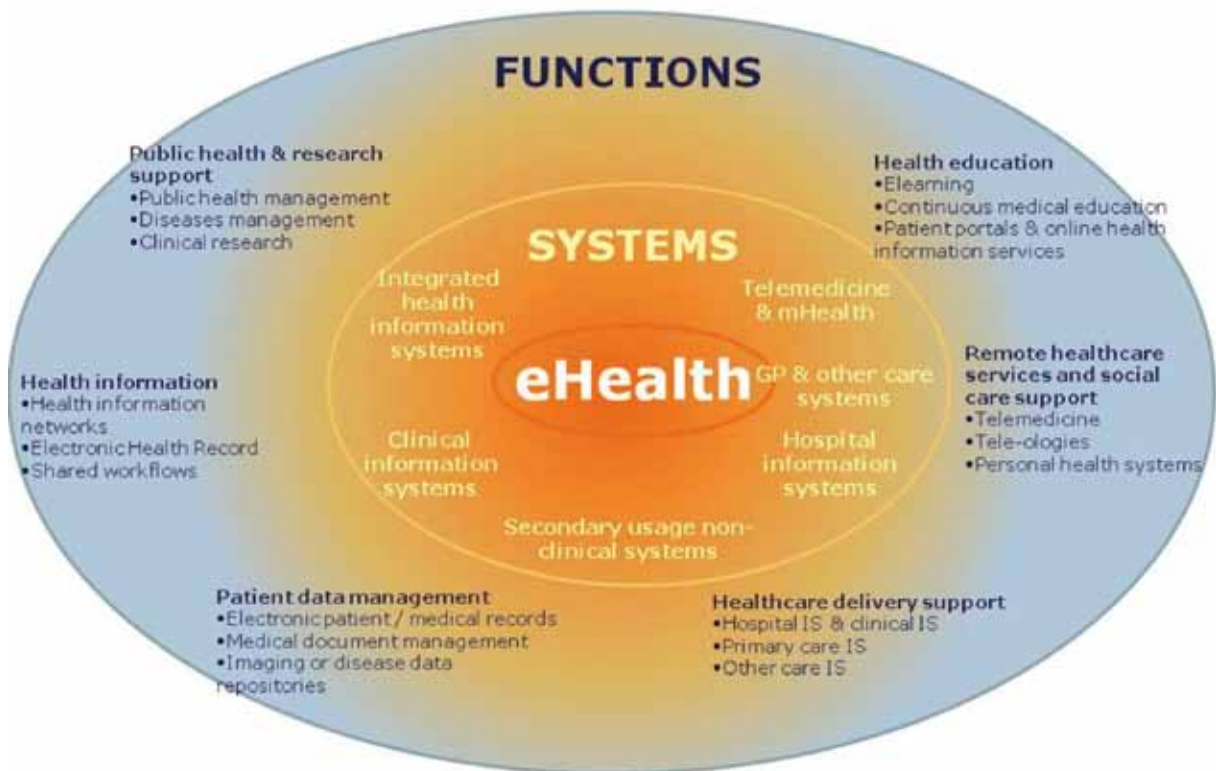
eHealth describes the application of information and communications technologies (ICTs) across the whole range of functions that affect the health sector. “eHealth”, “healthcare IT”, “health ICTs” and “health informatics” are synonymous. eHealth includes tools for health authorities and professionals as well as personalised health systems for patients and citizens. eHealth can therefore be said to cover the interaction between patients and health-service providers, provider-to-provider transmission of data, or peer-to-peer communications between patients and/or health professionals. It can also include health information networks, Electronic Patient Records, telemedicine services, and personal wearable and portable communicable systems for assisting prevention, diagnosis, treatment, health monitoring and lifestyle management.

### eHEALTH COMPRISES SIX TYPES OF SYSTEMS:

1. Hospital information system (HIS)
2. Clinical information system (CIS)
3. Other GP or speciality systems
4. Integrated health information exchange networks (HIE/EHR)
5. Telemedicine
6. Secondary-usage non-clinical systems (care analytics, public health and research)

### eHEALTH COVERS THE FOLLOWING SIX FUNCTIONS:

1. Healthcare delivery support systems
2. Patient Data management
3. Health information exchange
4. Remote healthcare services & social care support
5. Care analytics, public health & research support
6. Health education





## PART 2: GENERAL eHEALTH RELATED DEFINITIONS

### ACTIVE AND HEALTHY AGEING

Active and healthy ageing is the process of optimising opportunities for health, participation and security in order to enhance quality of life as people age. It applies to both individuals and population groups. 'Health' refers to physical, mental and social wellbeing. 'Active' refers to continuing participation in social, economic, cultural, spiritual and civic affairs, not just the simple ability to be physically active or to participate in the labour force.

### ACUTE CARE HOSPITAL

Acute care hospitals provide a wide range of diagnoses as well as inpatient care and treatment for seriously ill or injured patients. Typically, services include consultation with specialist clinicians; emergency treatment; routine, complex and life-saving surgery; specialist diagnosis procedures; close observation and short-term care of patients with worrying symptoms. Some acute care hospitals are specialised (e.g. maternity hospitals or cancer hospitals), while others are general, covering different clinical specialities.

### AMBIENT ASSISTED LIVING

Independent living supported by unobtrusive devices and systems within the home<sup>38</sup>.

### ANONYMISATION

The process used to strip personal data from all elements likely to help identify directly or indirectly the data subject (e.g. name, age, address, social security number, etc.). These elements are deleted to ensure re-identification is not possible.

### AUTHENTICATION

Authentication, in the context of eHealth information security, refers to the confirmation of the identity of a user requesting access to eHealth services and/or patient data. Its purpose is to verify whether or not the user really is who they claim to be. Authentication is not to be confused with Authorisation, which deals with rights particular users or user groups may or may not have. While Authentication deals with questions like: "Is this person really Dr. X?", Authorisation might ask "Does Dr. X have the right to access this specific kind of data?".

### BIG DATA

Big Data refers to datasets whose size is beyond the ability of typical database software tools to capture, store, manage, and analyse. Big Data also refers to the management of these ultra-large amounts of information (e.g. storage, aggregation, search, analysis, visualisation, and combination) and the use of the results to extract knowledge.

### BIOBANKS

Repositories that store biological samples for use in research. Biobanks give researchers access to data representing larger numbers of individual people than could be analyzed in previously used systems. Furthermore, samples in biobanks and the data derived from those samples can often be used by multiple researchers for multiple purposes. Biobanks have become a key resource, supporting many types of contemporary research like genomics and personalized medicine.

### BIOMARKERS

Biological parameters that can be used to identify a physiologic condition. They are traceable substances that are introduced into an organism as a means to examine organ function, or indicate a particular disease state or other aspects of health. Used in medical imaging, biomarkers are an essential element of predictive, preventive and Personalised Medicine.

### CARE COORDINATION<sup>39</sup>

The deliberate organisation of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of healthcare services. Organising care involves the marshalling of personnel and other resources needed to carry out all required patient care activities, and is often managed by the exchange of information among participants responsible for different aspects of care.

### CLINICAL PATHWAYS

Clinical pathways, also known as care pathways, critical pathways, integrated care pathways, or care maps, are one of the main tools used to manage the quality in healthcare concerning the standardisation of care processes. It has been proven that their implementation reduces the variability in clinical practice and improves outcomes. Clinical pathways promote organised and efficient patient care based on the evidence-based practice. Clinical pathways optimise outcomes in the acute care and homecare

38. Telescope project: [http://www.telehealthcode.eu/images/stories/telehea/pdf/fp1\\_glossary\\_of\\_terms\\_v3\\_final.pdf](http://www.telehealthcode.eu/images/stories/telehea/pdf/fp1_glossary_of_terms_v3_final.pdf)

39. US national Institute of health <http://www.ncbi.nlm.nih.gov/books/NBK44012/>

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settings. Generally clinical pathways refer to medical guidelines. However a single pathway may refer to guidelines on several topics in a well specified context.

### **CLOUD COMPUTING**

Cloud computing is internet-based computing, where shared servers provide computing power, storage, development platforms or software to computers and other devices on demand. This frequently takes the form of cloud services, such as 'Infrastructure as a Service' (IaaS), 'Platform as a Service (PaaS)' or 'Software as a Service' (SaaS). Users can access web-based tools or applications through a web browser or via a cloud-based resource like storage or computer power as if they were installed locally, eliminating the need to install and run the application on the customer's own computers and simplifying maintenance and support.<sup>40</sup>

There are several possible deployment models for clouds, the most important being public, private and hybrid.

- **A PUBLIC CLOUD** is one in which a service provider makes resources, such as applications and storage, available to the general public over the internet, for maximum cost-efficiency, resilience and elasticity.
- **PRIVATE CLOUD** is infrastructure operated solely for a single organisation. The resources have all the key characteristics of the public cloud (see above) but are dedicated to one single organisation, giving it more control over security and access, and the ability to tailor/customise characteristics offered by public cloud.
- **HYBRID CLOUD INFRASTRUCTURE COMBINES** the first two approaches, with sensitive applications and data in a private cloud and more generic systems and processes in a public cloud.

### **COMPOUND ANNUAL GROWTH RATE**

Compound annual growth rate (CAGR) is an average growth rate over a period of several years.

### **CONFORMANCE**

Refers to the ability of a product or system to perform a set of functions according to specifications that are defined within a standard. Testing whether a system conforms to a set of standards is called conformance testing.

### **CONSENT**

Data subject consent means any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed.

### **DATA ANALYTICS**

The discovery and communication of meaningful patterns in data, in order to make sense of the 'Big Data'. Data analytics techniques analyse datasets to describe, predict, and improve performance. Commonly applied in business, data analytics are increasingly used in healthcare.

### **DATA CONTROLLER<sup>41</sup>**

The natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; where the purposes and means of processing are determined by national or Community laws or regulations, the controller or the specific criteria for his nomination may be designated by national or Community law.

### **DATA PROCESSOR<sup>42</sup>**

A natural or legal person, public authority, agency or any other body which processes personal data on behalf of the controller.

### **DATA SECURITY**

The protection of personal data from unauthorised or unintentional loss, theft, access, use, modification, or disclosure.

### **EDISPENSATION (ELECTRONIC DISPENSATION)**

eDispensation – or eDispensing – is defined as the act of electronically retrieving a prescription and dispensing medicine to the patient as indicated in the corresponding ePrescription. Once the medicine has been dispensed, the dispenser sends an electronic report on the medicine(s) dispensed.

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40. COCIR definition, eHealth Toolkit, May 2011

41. [http://ec.europa.eu/justice/data-protection/document/review2012/com\\_2012\\_11\\_en.pdf](http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf)

42. [http://ec.europa.eu/justice/data-protection/document/review2012/com\\_2012\\_11\\_en.pdf](http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf)



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### **ELECTRONIC PATIENT RECORD (EPR)**

An Electronic Patient Record (EPR) is a record in digital format containing medical information about a patient. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, vital signs, personal statistics like age and weight, and billing information.

There are different types of Electronic Patient Records:

- Electronic medical record / Electronic Patient Record
- Patient summary
- Personal health record

### **ELECTRONIC MEDICAL RECORD (EMR) / ELECTRONIC PATIENT RECORD (EPR)**

Electronic Patient Record (EPR), Electronic Medical Record (EMR), Computerised Patient Record (CPR) are synonymous. They refer to an individual patient's medical record in digital format generated and maintained by a care provider, such as a hospital or a physician's office. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunization status, laboratory test results, radiology images, and billing information. The purpose of an EPR/EMR can be understood as a complete record of patient encounters that allows the automation and streamlining of the workflow in health care settings and increases safety through evidence-based decision support, quality management, and outcomes reporting.

### **EMPOWERMENT<sup>43</sup>**

A process through which people gain or are afforded greater control over decisions and actions affecting their lives.

### **ENCRYPTION**

Encryption is the process of encoding messages or information in such a way that only authorised parties can read it. Encryption does not prevent hacking but it reduces the likelihood that the hacker will be able to read the data that is encrypted.

### **ENTERPRISE IT**

Enterprise IT is synonymous with Hospital IT. See Hospital IT definition.

### **EPRESCRIPTION (ELECTRONIC PRESCRIPTION)**

An ePrescription is an electronic prescription: a medicinal prescription, e.g. a set of data like drug ID, drug name, strength, form, dosage and/or indication(s), provided in electronic format.

The term 'ePrescription' may cover different functionalities, and depending on national viewpoints, the definition of ePrescription may vary. In general, the term 'ePrescription' may refer to the following features:

- Electronic medication record of an individual
- Informed prescription with electronic decision support
- Electronic transmission of a prescription.

In this framework, the ePrescription service is understood as the prescription of medicines using software, the electronic transmission of the prescription from the prescriber (the healthcare professional) to a dispenser (e.g. pharmacy), where the prescription is electronically retrieved, the medicine is given to the patient and information about the dispensed medicine(s) is reported electronically.

### **EVIDENCE-BASED MEDICINE<sup>44</sup>**

Evidence-based medicine is a medicine that bases clinical decisions from evidence coming from the analysis of clinical data. It is defined in medical literature as the 'conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'.

### **GENOTYPE**

Genotype refers to the genetic makeup of an organism, such as a human being.

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43. Telescope [http://www.telehealthcode.eu/images/stories/telehea/pdf/tp1\\_glossary\\_of\\_terms\\_v3\\_final.pdf](http://www.telehealthcode.eu/images/stories/telehea/pdf/tp1_glossary_of_terms_v3_final.pdf)

44. [http://en.wikipedia.org/wiki/Evidence-based\\_medicine](http://en.wikipedia.org/wiki/Evidence-based_medicine)

### HEALTH DATA<sup>45</sup>

Any information relating to the health of an identified or identifiable natural person. It can include demographics (age, sex, date of birth etc), clinical information (blood type, medication history, allergies, medical images, laboratory results, diet), genetic information (genotype, family disease history), disease information (cancer, HIV-AIDS, Alzheimer etc), medical interventions (delivery, abortion, surgery interventions), long-term care information etc.

### HOSPITAL DIAGNOSIS IMAGING WORKFLOW

This use case supports the workflow related to imaging diagnostic tests performed inside a healthcare institution, for both identified orders and unknown orders, related to both identified patients and unidentified or misidentified patients.

### HOSPITAL IT

Hospital IT – also often referred to as Enterprise IT – is a generic term referring to ICT-based products, systems, solutions and services used in hospitals to:

- Manage healthcare processes
- Manage the hospital administrative and business processes

Hospital IT includes Hospital Information Systems (Patient Administration Systems, Finance and Accounting Systems, Business Process Support, Logistics and Resource Systems) and Clinical Information Systems (Radiology Information Systems, Oncology Information Systems, Computerised Physician Order Entry Systems, Electronic Patient Records etc).

### HOSPITAL LABORATORY WORKFLOW

This use case supports the workflow related to tests performed by a clinical laboratory inside a healthcare institution, for both identified orders and unknown orders, related to both identified patients and unidentified or misidentified patients.

### EID

eID is the acronym for electronic identification. eID is enabled by the collection of identity attributes in an electronic form.

### IDENTIFICATION

Performance of tests to enable a data processing system to recognise entities and individuals.

### ELECTRONIC IDENTITY

Identity data (of a person) usable in electronic format.

### IMAGING NETWORK

An imaging network is an ecosystem of connected care providers, allowing the seamless exchange of medical imaging and documents and related clinical data.

### INFORMATION SYSTEM (IS)

An Information System (IS) is any combination of information technology and people's activities using that technology to support operations, management, and decision-making. In a very broad sense, the term information system is frequently used to refer to the interaction between people, algorithmic processes, data and technology. In this sense, the term is used to refer not only to the information and communication technology (ICT) an organisation uses, but also to the way in which people interact with. This technology in support of business processes.

### INFOSTRUCTURE

eHealth Infostructure should be understood as the foundation layer containing all data structures, codifications, terminologies and ontologies, data interoperability and accessibility standards, stored information and data, as well as rules and agreements for the collection and management of these data and the tools for their exploitation. At European level, such a European infostructure may be composed of biomedical and health/medical research and knowledge databases, public health data repositories, health education information, electronic patient and personal health records systems, data warehouses etc.

### INTEGRATED CARE

Integrated care is a trend in healthcare reforms focusing on more coordinated and integrated forms of care provision. Integrated care may be seen as a response to the fragmented delivery of health and social services being an acknowledged problem in many health systems. WHO defines integrated care as a concept bringing together inputs, delivery, management and organisation of

45. [http://ec.europa.eu/justice/data-protection/document/review2012/com\\_2012\\_11\\_en.pdf](http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf)

services related to diagnosis, treatment, care, rehabilitation and health promotion. Integration is a means to improve services in relation to access, quality, user satisfaction and efficiency. Furthermore, the WHO defines “integrated service delivery” as “the organisation and management of health services so that people get the care they need, when they need it, in ways that are user-friendly, achieve the desired results and provide value for money.”

### INTEGRATED HEALTH INFORMATION NETWORKS

Networks supporting the exchange, processing and storage of health information. Integrated means that these networks are part of a broader IT infrastructure connecting different applications, servers or data centres, e.g. in a hospital or in a chain of hospitals, or even in local/regional or national IT infrastructure.

### INTEGRATED PERSONAL HEALTH SYSTEMS<sup>46</sup>

Integrated Personal Health and Care Services address the health and social care needs of individuals outside of care institutions and support the work of care providers in an integrated fashion:

- They can integrate assistance, remote monitoring of chronic diseases, wellness and fitness
- They are produced as a result of integration of different institutional and information systems.

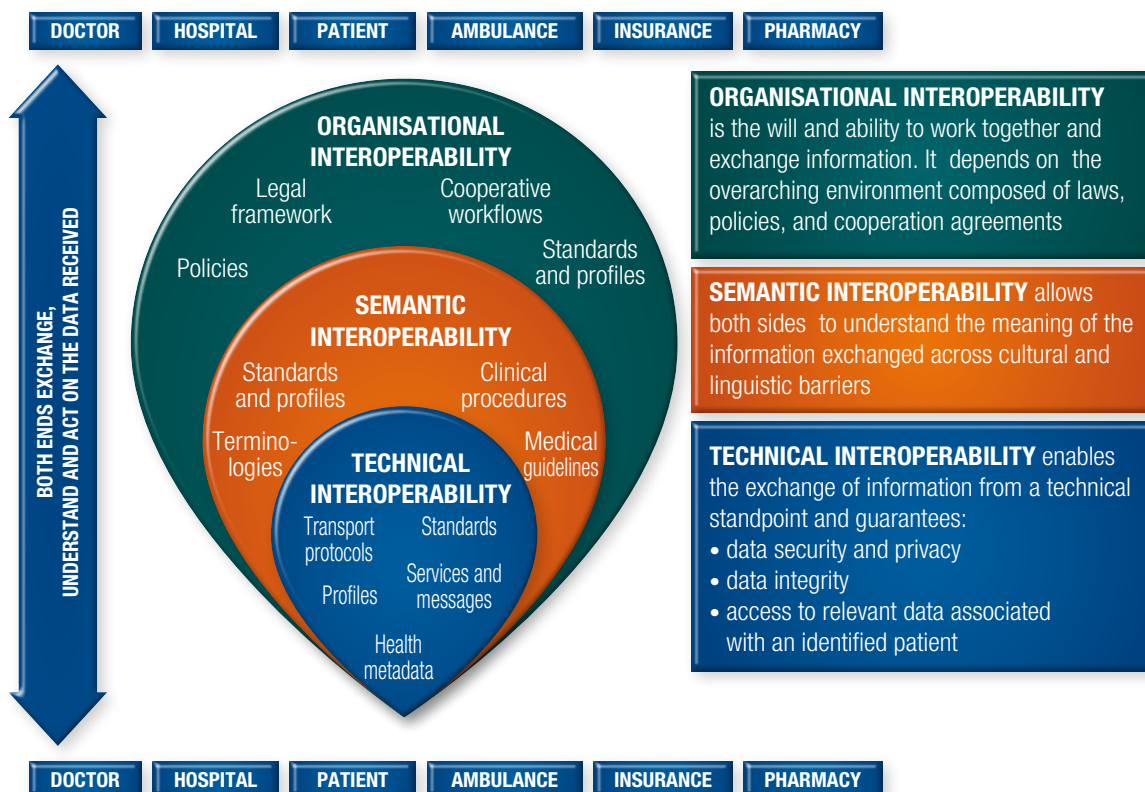
They are personal and possibly personalised in the way they gather, process and communicate data (for feedback/action).

### INTEROPERABILITY

eHealth interoperability means the ability of two or more eHealth systems to use and exchange both computer interpretable data and human understandable information and knowledge.

There are three levels of interoperability - organisational, semantic and technical:

1. Organisational interoperability – also referred to as legal, process or cooperability interoperability – refers to the broader environment of laws, policies, procedures and bilateral cooperation needed to allow the seamless exchange of information between different organisations, regions and countries.
2. Semantic interoperability refers to the ability to ensure that the precise meaning of exchanged information is interpretable by any other system or application not initially developed for this purpose.
3. Technical interoperability means the ability of two or more ICT applications, to accept data from each other and perform a given task in an appropriate and satisfactory manner without the need for extra operator intervention.



46. Institute for Prospective Technological Studies – Strategic Intelligence Monitor on personal health Systems

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### LABORATORY INFORMATION SHARING

This use case supports the secured sharing (publishing, finding and retrieving) of laboratory reports and test results across a group of affiliated hospitals and practices within a region or nation. This use case provides ambulatory providers with online easy access to new laboratory test results for their patients, as well as comparison with earlier tests and prevents duplicated tests.

### LEGACY SYSTEM

A legacy system is the existing technology, computer systems, application programmes and IT infrastructure that continues to be used, typically because it still functions for the users' needs, even though newer technology or more efficient methods of performing a task may be available.

### MEDICAL IMAGING

The technique and process used to create images of the human body to reveal, diagnose, or examine a disease. Medical imaging is critical for early diagnosis and better evaluation of the treatment effect for improved outcomes. Medical Imaging has become a cornerstone of modern medicine in many disciplines: oncology; traumatology, musculoskeletal disorders, etc.

### MEDICAL IMAGING INFORMATION SHARING

Imaging information sharing supports the secured sharing (publishing, finding and retrieving) of reports and imaging studies across a group of affiliated hospitals and practices within a region or nation. This use case provides ambulatory providers with easy online access to patients' imaging results, as well as to prior examinations of imaging departments (for comparison or to avoid duplicating imaging procedures).

### mHEALTH – MOBILE HEALTH

Mobile health, or mHealth, is the provision of eHealth services and information that relies on mobile and wireless technologies. Similarly to eHealth, of which it is part, mHealth describes a broad set of technologies that can support a variety of health-related services, and is not a separate category of services in itself. Mobile technologies are utilised across the range of healthcare, social care, wellness and prevention, and form an integral part of telemedicine, telehealth and telecare.

### MOLECULAR IMAGING<sup>47</sup>

Molecular Imaging is a discipline at the intersection of molecular biology and in vivo imaging. It enables the visualisation of the cellular function and the follow-up of the molecular process in living organisms without perturbing them. MI is used in the field of cancer, neurological and cardiovascular diseases. This technique also contributes to improving the treatment of these disorders by optimising the pre-clinical and clinical tests of new medication.

### NEXT GENERATION SEQUENCING

Next generation sequencing (NGS) is a new method for sequencing genomes at high speed, at low cost and with great accuracy. It is also known as second generation sequencing (SGS).

### OLOGIES

-ology, a suffix derived from the Greek logos, refers to the study of, or a speciality in a given scientific or medical field, e.g. oncology, pathology, radiology, etc.

### -OMICS<sup>48</sup>

The English-language neologism -omics informally refers to a field of study in biology ending in -omics, such as genomics, proteomics or metabolomics. The related suffix -ome is used to address the objects of study of such fields, such as the genome, proteome or metabolome respectively. -Omics aims at the collective characterisation and quantification of pools of biological molecules that translate into the structure, function, and dynamics of an organism or organisms.

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47. [http://en.wikipedia.org/wiki/Molecular\\_imaging](http://en.wikipedia.org/wiki/Molecular_imaging)

48. <http://en.wikipedia.org/wiki/Omics>



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## PATIENT CENTRED CARE

Healthcare that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.

## PATIENT REGISTRY

Patient registries are collections of secondary data related to patients with a specific diagnosis, condition, or procedure. In its most simple form, a disease registry could consist of a collection of paper cards kept inside a box by an individual doctor. Most frequently, registries vary in sophistication from simple Excel spreadsheets which can only be accessed by a small group of doctors to very complex databases which are accessed online across multiple institutions. They can give healthcare providers (or even patients) reminders to check certain tests in order to reach certain quality goals. Patient registries are less complex and simpler to set up than Electronic Medical Records/Electronic Patient Records. An EMR/ EPR keeps track of all the patients a doctor follows while a registry only keeps track of a small sub-population of patients with a specific condition.

## PATIENT SELF-MANAGEMENT

The systematic provision of education and supportive interventions by healthcare staff to increase patients' skills and confidence in managing their health problems, including regular assessment of progress and problems, goal setting, and problem-solving support. Self-management support programs may be able to help patients with conditions such as asthma, cardiovascular disease, depression, diabetes, heart failure, and migraine headaches (Pearson et al., 2007). In addition, self-management programmes may support patients in managing other health-related activities that may not be specific to a given condition, such as medication management or prevention and wellness.

## PATIENT SUMMARY<sup>49</sup>

A Patient Summary is a sub-set of an Electronic Medical Record. A Patient Summary is a concise clinical document which provides an electronic patient health data set applicable both for unexpected, as well as expected, healthcare contact.

The primary application of an electronic patient summary is to provide the healthcare professional with a dataset of essential and understandable health information needed in case of unexpected or unscheduled care (e.g. an emergency or accident) or in the case of planned care (e.g. the patient is in another area and needs to consult a healthcare professional other than their regular contact person).

The Patient Summary does not include a detailed medical history, details of the clinical condition, or the full set of the prescriptions and medicines dispensed but includes data such as:

- Patient's general information (mandatory)
- Medical summary (mandatory)
- Medication summary (mandatory)

A patient may have more than one electronic patient summary.

## PERSONAL DATA<sup>50</sup>

Any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly; in particular by reference to an identification number or to one or more factors specific to their physical, physiological, mental, economic, cultural or social identity.

## PRIVACY<sup>51</sup>

In healthcare, privacy stands for the generic interest a patient has in being able to control who has access to his or her information, and keep his/her information away from public view.

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49. epSOS definition: [http://www.epsos.eu/faq-glossary/glossary.html?tx\\_a21glossaryadvancedoutput\\_pi1%5Bchar%5D=p&cHash=a6f1fa3be9712f8a355813734283d2ee](http://www.epsos.eu/faq-glossary/glossary.html?tx_a21glossaryadvancedoutput_pi1%5Bchar%5D=p&cHash=a6f1fa3be9712f8a355813734283d2ee)

50. [http://ec.europa.eu/justice/data-protection/document/review2012/com\\_2012\\_11\\_en.pdf](http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf)

51. WHO - Global Observatory for eHealth- Volume 5 – legal frameworks for eHealth – 2012

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### PERSONAL HEALTH RECORD

A personal health record – or PHR – is a health record that is initiated and maintained by an individual. Other health records such as Electronic Patient Record (EPR) or electronic medical record (EMR) are generated and maintained within an institution, such as a hospital, clinic, or physician's office.

### PERSONAL HEALTH SYSTEMS (PHS)

Personal Health Systems (PHS) assist in the provision of continuous, quality controlled, and personalised health services, including diagnosis, treatment, rehabilitation, disease prevention and lifestyle management, to empowered individuals regardless of location. PHS consist of intelligent ambient and/or body devices (wearable, portable or implantable), intelligent processing of the acquired information and active feedback from health professionals or directly from the devices to the individuals.

### PERSONALISED MEDICINE (NEW)

Personalised Medicine is an evolution from today's medical model of standardised clinical pathways and drugs licensed for an entire population, towards an approach which recognises the differences between individuals in their health risks, and their responsiveness to treatments. We have already embarked on this journey with Stratified Medicine, which attempts to cluster populations into smaller groups, based on their phenotypic characteristics. As more detailed knowledge becomes available, including genomic and proteomic data, we now need to consider how to evolve and adapt preventive, diagnostic, therapeutic and follow-up actions to each individual person. In addition, the adaption needs to take into account clinical information, the individual's specific epidemiologic and social context, personal preferences and lifestyle etc. Over time, as accuracy and confidence levels increase, we will move closer to the goal of Precision Medicine, completely customising the care to the individual, to optimise outcomes or prevent the incidence of any disease. In COCIR's view, although –omic information and corresponding research are very important, Personalised Medicine goes beyond using genomic information for personalising treatment. Personalised Medicine must be seen in the context of a holistic approach to healthcare, in which the patient becomes the central stakeholder.

### PHENOTYPE

A phenotype is the composite of an organism's observable characteristics or traits, such as its morphology, development, biochemical or physiological properties, behavior, and products of behaviour. A phenotype results from the expression of an organism's genes as well as the influence of environmental factors and the interactions between the two.

### PSEUDONYMISATION

Pseudonymisation is the process of disguising identities - the aim of such a process is to be able to collect additional data relating to the same individual without having to know their identity. This is particularly relevant in the context of research and statistics. Disguising identities can also be done in a way that no re-identification is possible, e.g. by one-way cryptography, which creates in general anonymised data.

### PROFILE

A profile is a selection of specifications and options from existing standards, combined to serve a specific use case. Profiling is conducted in order to achieve interoperability between different products and implementations.

### RADIOGENOMICS

Radiogenomics refers to non-molecular imaging biomarkers. Radiogenomics links radiological image information with genomic data, and together with the development and integration of imaging biobanks can be expected to be both integral and critical to the advance of Personalised Medicine.

### SECONDARY USAGE NON-CLINICAL SYSTEMS

Secondary usage non-clinical systems include:

- Systems for health education and health promotion of patients/citizens such as health portals or online health information services.
- Specialised systems for researchers and public health data collection and analysis such as bio-statistical programmes for infectious diseases, drug development, and outcomes analysis

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### **SOFTWARE AS A SERVICE (SAAS)**

Software as a service, sometimes referred to as “software on demand” is software that is deployed over the internet and/or is deployed to run behind a firewall on a local area network or personal computer. With SaaS, a provider licenses an application to customers either as a service on demand, through a subscription, in a “pay-as-you-go” model, or at no charge. This approach to application delivery is part of the utility computing model where all of the technology is in the “Cloud” accessed over the internet as a service.

### **STANDARD**

A standard is an agreed, repeatable way of doing something. It is a published document that contains a technical specification or other precise criteria designed to be used consistently as a rule, guideline, or definition. Standards help to make life simpler and to increase the reliability and the effectiveness of many goods and services we use. Standards are created by bringing together the experience and expertise of all interested parties such as the producers, sellers, buyers, users and regulators of a particular material, product, process or service.

### **STRUCTURED DATA**

Data organised in such a way that the different attributes, e.g. patient name, diagnosis and medication are interpretable by an IT system.

### **TELE-ASSISTANCE**

Tele-assistance can be a medical act when a doctor remotely assists another doctor carrying out a medical or surgical act. The doctor can also assist another health professional who carries out an act of care or imaging, even within the framework of an emergency, to remotely assist a first aid worker or any person providing medical assistance someone in danger while waiting for the arrival of a doctor.

### **TELECARE**

Telecare designs systems and services capable of social alert and social services. Telecare is used mainly to monitor the situation of people dependent on external help (i.e. elderly or disabled people) in the home setting.

### **TELECARDIOLOGY**

Telecardiology covers the remote collection of cardiology data, mostly ECG data, and their transmission to a service centre. In the centre, the data are evaluated by qualified staff who give advice to a patient or another healthcare provider. In emergencies, the service centre may also trigger rescue measures. Data transmission can either take place continuously or at clearly defined points of time. Data collection can take place either at the patient's home or mobile.

### **TELECONSULTATION**

Teleconsultation is a medical act where the patient is present, and may be assisted by a healthcare professional. The healthcare professional may or may not be a medical doctor.

### **TELEDERMATOLOGY**

Teledermatology describes the transmission of visible light images (photos or videos) of disorders of the human skin for classification and diagnosis. It can take the form of primary as well as secondary diagnosis. Detection and classification of skin cancers is a typical example. Since dermatology is a highly-specialised discipline and many patients will see a general practitioner first, the use of teledermatology offers great potential to shorten the diagnostic process and speed up the start of appropriate treatment.

### **TELE-EXPERTISE**

Tele-expertise is a remote medical act between at least two healthcare professionals without the presence of the patient for decision purpose.

### **TELEHEALTH (Includes REMOTE PATIENT MANAGEMENT or “RPMT”)**

The term telehealth covers systems and services linking patients with care providers to assist in diagnosing and monitoring, as well as the management and empowerment of patients with long-term conditions (chronic patients). Telehealth solutions use devices

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(interactive audio, visual and data communication) to remotely collect and send data to a monitoring station for interpretation and to support therapy management programmes and improve patients' knowledge and behaviour. Telehealth solutions comprise systems and components (patient interfaces in hardware and software, sensors/peripherals, operating software and applications intended for care provider usage, clinical content and intelligence; data transmission, storage and intelligent routing) as well as supporting services (system operation, logistics, financial services etc).

### **TELE-INTERVENTION**

Tele-intervention is a therapeutic medical act which is performed remotely by a physician on a patient, without or with the local presence of other healthcare professional(s) e.g. telesurgery.

### **TELEMEDICINE**

Telemedicine is the overarching definition covering Telehealth, Telecare and teledisciplines. Telemedicine can be defined as the delivery of healthcare services through the use of information and communication technologies (eHealth), including wireless and mobile connectivity (mHealth), in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (e.g. teleradiology, telesurgery) or a healthcare professional and a patient (e.g. telemonitoring of the chronically ill such as those with diabetes and heart conditions, telepsychiatry etc). Telemedicine includes all areas where medical or social data is being sent/exchanged between at least two remote locations, including both care provider to patient/citizen as well as doctor-to-doctor communication.

### **TELEMONITORING**

Telemonitoring refers to systems and services using devices to remotely collect/send vital signs to a monitoring station for interpretation.

Telemonitoring is the remote exchange of physiological data between a patient at home and medical staff at hospital to assist in diagnosis and monitoring (this could include support for people with lung function problems, diabetes etc). It includes (amongst other things) a home unit to measure and monitor temperature, blood pressure and other vital signs for clinical review at a remote location (for example, a hospital site) using phone lines or wireless technology.

### **TELE-OPHTHALMOLOGY**

Tele-ophthalmology describes the remote diagnosis of medical conditions of the human eye. Similar to teledermatology, patients may not have immediate access to an ophthalmologist. Ophthalmology not only diagnoses typical diseases of the eye but can also generate useful information on other diseases, e.g. diabetes and cardiac conditions and related secondary symptoms. Data typically take the form of photos or videos.

### **TELEPATHOLOGY**

Telepathology enables remote staff pathologists, and third-party providers, to securely share images of anatomical pathology specimens to complete primary and non-primary diagnostic evaluation, and to also seek expert second opinions, and primary interpretation of urgent cases, from operating rooms.

### **TELEPSYCHIATRY**

Telepsychiatry is a form of teleconsultation by a psychiatrist of a patient suffering from mental disorder.

### **TELERADIOLOGY**

Teleradiology Information Systems (IS) enables secure remote evaluation of digital diagnostic studies (CT scans, MRIs and X-Rays). This technology enables both remote staff radiologists and third-party providers to complete primary and non primary diagnostic studies from any location. It encompasses hospital-to-home teleradiology for out-of-hours healthcare coverage i.e. remote working for radiologists being part of the hospital radiology department. It also covers outsourcing to other imaging centers or commercial teleradiology companies that provide outsourcing services for image interpretation (night and/or day reads).

## TELESCREENING

Telescreening describes the use of a first or second opinion through a remote connection in screening programmes. Either medical data is transferred to a remote specialist for primary evaluation, e.g. in the case that a specific medical qualification is required. Another scenario involves a second opinion in order to increase the quality of the screening process. An example in the form of teleradiology would be the use of screening centres in mammography screening. The data transmitted during telescreening can take any form from digital X-Ray images to video files or ECG or laboratory data.

## TELESURGERY

Telesurgery describes the remote controlling of surgical apparatus, e.g. a surgical robot, by an experienced surgeon or the remote advice provided by an experienced surgeon to the surgeon on duty in the operating theatre. In the latter case, a live video connection and an audio connection between the two surgeons is sufficient. In the former case, a data link between the surgical apparatus on site and the remote manipulation tool is required.

## UNSTRUCTURED DATA

Unstructured Data (or unstructured information) refers to information that either does not have a pre-defined data model or is not organised in a pre-defined manner. Unstructured information is typically text-heavy, but may contain data such as dates, numbers, and facts as well. This results in irregularities and ambiguities that make it difficult to understand using traditional computer programmes as compared to data stored in fielded form in databases or annotated (semantically tagged) in documents.

## UNIQUE IDENTIFIER

In healthcare, unique identifier is a unique number that has been assigned to healthcare consumers (patients), and to healthcare providers and organisations that provide health services. The aim of unique identifiers is to ensure that individuals and providers can have confidence that the right health information is associated with the right individual.

## USE CASE

In healthcare, a unique use case refers to a situation or a need for which eHealth information exchange needs to be developed. A use case helps to identify the relevant real world requirements. Use case descriptions are independent of technical details and focus on actions and information flow in the clinical world. Profiles are developed for each use case to ensure interoperability. The most common use cases referred to in eHealth are information exchange associated with patient summary, ePrescription, medical imaging exchange, laboratory results exchange.

**CLINICAL USE CASE:** A clinical use case refers to scenarios and terms of the clinical world rather than mentioning computer-related terms.

**TECHNICAL USE CASE:** A technical use case is a use case that refers to application scenarios, but already assumes some technical measures or components. Technical use cases typically help in the selection of existing specifications and design of solution components.

## VITAL SIGN MONITORING<sup>52</sup>

Vital signs are to be understood as a set of physiological indicators, which reflect the overall status of the body. With the help of technologies they can be checked regularly to assess body functions of an individual making it possible to remotely monitor the patient or user status, without the need of a care giver to be present. The measurement and the resulting data are either collected discretely meaning at predetermined intervals called spot checking or continuously. Originally automated vital signal monitoring was used in Intensive Care Units (ICUs), Cardiac Care Units (CCUs) and Operating Rooms (ORs). Today spot checking certain parameters forms part of the procedures for most medical physical examinations. In addition, it can be used to determine training effects.

## VENDOR NEUTRAL ARCHIVING (VNA)<sup>53</sup>

A VNA provides image storage, management, archiving and routing functions for one or more medical imaging documentation and archiving systems. It may also include integration to a clinical viewer offering secure access to standard imaging data from existing workstations anywhere on the network. The viewer is generally considered an external component to the VNA.

52. Institute for Prospective Technological Studies – Strategic Intelligence Monitor on personal health Systems

53. See Part 2 on VNA for a more detailed definition.



## PART 3: HOSPITAL INFORMATION SYSTEMS (HIS)

Hospital Information Systems manage the administrative and financial aspects of a hospital (patient administration, finance, accounting, logistics, human resources, materials management etc). This includes paper-based information processing as well as data processing machines. Hospital Information Systems include business process support systems, finance and accounting systems, logistics and resource systems, patient administration systems.

### 3.1. BUSINESS PROCESS SUPPORT

Systems designed to support the business processes of a hospital. They collect, integrate, analyse and present business information to improve business decision-making.

#### **BUSINESS INTELLIGENCE SYSTEMS (BI)**

Business Intelligence (BI) systems refer to technologies, applications and practices for the collection, integration, analysis, and presentation of business information to improve business decision-making by using fact-based/data-driven decision support systems. BI systems provide historical, current and predictive views of business operations using data from a (clinical) data warehouse and operational data. The emerging integrated clinical/financial BI systems approach therefore combines traditional sources (such as human resources, cost accounting and financial reporting) with rich clinical data from computer-based patient record/medical records (EPR/EMR).

However, a BI system is much more than a data warehouse. Its purpose is to provide insights that affect and improve business/clinical processes and all the associated outcomes (clinical, financial etc.) BI also has a real-time, immediate dimension. Results can be either predictive or correlative in nature.

#### **CLINICAL DATA WAREHOUSING SYSTEMS (CDW)**

Data Warehousing Systems (CDW) are integrated systems of patient-related clinical data allowing the collection and normalisation of data from disparate clinical sources into a database designed to support management clinical decision-making, performance analysis purposes or research. CDW can be standalone solutions based on database platforms and integration standards, or integrated with an Electronic Patient Record/Electronic Medical Record (EPR/EMR) solution or built at regional level as is the case in Norway and Sweden. In all cases, CDW are usually tied to the Master Patient Index (MPI).

#### **QUALITY MANAGEMENT SYSTEMS (QMS)**

Also called Assurance Information Systems, QMS support the monitoring of the overall performance and quality of clinical care by analysing, comparing and treating information of detailed clinical practices patterns and parameters. Quality Management / Assurance IS might also include compliance/audit features, for example by asking if the care which was documented matched the care given). It also has a real-time, immediate dimension. Results can be corrective and preventive in nature.

### 3.2. FINANCE & ACCOUNTING SYSTEMS

Information systems designed for the finance and accounting departments of hospitals to manage financial and accounting processes. They include – amongst others – Coding Information Systems, Financial Accounting and Controlling Information Systems.

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### **CODING INFORMATION SYSTEMS**

Coding Information Systems are used to collect and code clinical service information for patient billing, insurance claims, activity analysis and cost accounting. They may include DRG-Management features. They enable personnel to find and use complete and accurate codes and code modifiers for procedures and diagnostics to optimize billing and reimbursement. They are rarely a standalone system and can be part of Patient Administration System either directly or through the Electronic Patient Record / Electronic Medical Record (EPR/EMR) depending on each country's coding workflow specificities (in Germany, for example, coding is performed by physicians). Coding Information Systems are usually associated with care administration but have also clinical relevance with specific code for clinical purposes or research.

### **FINANCIAL ACCOUNTING & CONTROLLING INFORMATION SYSTEMS**

Financial Accounting & Controlling Information Systems record and process accounting transactions within a variety of functional modules, including Accounts receivable (AR), Accounts payable (AP), General ledger (GL), Billing, Stock/Inventory, Purchase Requisition and Purchase Order (PO), Debt Collection (DC), Expenses, Inquiries, Payroll, Timesheets, and Controlling and Financial Reporting. Coding Information Systems might be part of this or provided as a separate Information System. Financial Accounting & Controlling Information Systems can be stand-alone systems or part of an Enterprise Resource Planning (ERP).

## **3.3. LOGISTICS AND RESOURCE SYSTEMS**

Logistics and resource systems are information systems designed to manage the logistics and resources of a hospital. They include – among others – enterprise resource planning systems, Human Resources management systems, supply chain management systems etc.

### **ENTERPRISE RESOURCE PLANNING SYSTEMS (ERP)**

Enterprise Resource Planning Systems are business management systems that integrate multiple business applications including human resources and payroll management, materials management, supply chain management, financials and accounting management as well as customer relationship management (CRM) by providing an automated and integrated view of business information and reports of data from several operational areas.

### **FACILITY & EQUIPMENT MANAGEMENT SYSTEMS**

Facility & Equipment Management systems control and monitor facilities and equipments, describe and track their deployment, maintain the clinical infrastructure and optimise resource utilization. Additionally, they can manage the interactions and activities from the selection and acquisition, inspections / maintenance through to the eventual retirement/disposal of medical equipment governed by related policies and procedures. Available as standalone tools/systems (e.g. Medical Equipment Management System - MEMS; Facility Management System - FMS) or as part of an Enterprise Resource Planning (ERP) system or a Hospital Information System. Such systems require integration with key clinical systems (orders etc).

### **HUMAN RESOURCES MANAGEMENT SYSTEMS (HRM)**

Human Resource Management Systems manage the administration of personnel, including personnel planning/staff/nurse scheduling, employee time and attendance tracking/labour time assessment, payroll and controlling. Individual functions may be stand-alone solutions or part of an Enterprise Resource Planning (ERP) system including Payroll and Human Resources. In healthcare delivery systems operated by government (e.g. national health systems), HRM systems may reside on government systems.

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### **SUPPLY CHAIN MANAGEMENT (SCM)/MATERIALS MANAGEMENT SYSTEMS**

Supply Chain Management Systems manage the processes of planning, implementing and controlling all movement and storage of materials and inventory from point-of-origin to point-of-consumption. Key functionalities include: purchase order processing, inventory management, warehouse / materials management, supplier relationship management/sourcing. SCM are available as standalone tools/systems or as part of an Enterprise Resource Planning (ERP) system. Standalone systems/tools may also be integrated with Enterprise Resource Planning (ERP) solutions. SCM require the integration with key clinical systems (orders etc.)

## **3.4. PATIENT ADMINISTRATION SYSTEMS**

A patient administration system is one of the earliest components of a hospital computer system which manages the administrative side of the relations with a patient.

Patient administration systems include - among other things - admission, discharge and transfer systems, master patient index systems, patient relationship management systems, scheduling of critical resources or facilities systems.

### **ADMISSION, DISCHARGE & TRANSFER SYSTEMS (ADT)**

Also called registration systems, ADT systems include pre-registration, patient history (administrative), patient admission and discharge transfer functions. They are rarely standalone systems and are mainly part of an overarching Patient Administration System (PAS).

### **MASTER PATIENT INDEX SYSTEMS (MPI OR EMPI)**

MPI systems maintain a unique patient identifier and a single master index of all patients, which references all patient indices within a single facility (e.g. hospital or a group of hospitals) to correctly identify and share patient information across linked IT systems with multiple authorised users. MPI systems also provide additional search functionality for specific patients including full name, partial names, address, ID numbers, etc. MPI systems are rarely a standalone system and are very often an integral component of a Patient Administration System (PAS) or electronic patient records (EPR)/electronic medical records (EMR). MPI is for a single facility whereas EMPI is a unique patient identifier for multi-facilities (who may each identify patients non-uniquely across facilities). To accurately match and link records across systems, a standalone EMPI has proven integration with these systems, scalability to support real-time identification across millions of records and most importantly a matching algorithm that can take data from different systems and create a unified view.

### **PATIENT RELATIONSHIP MANAGEMENT SYSTEMS (PRM)**

PRM refers to the use of IT for identifying and anticipating patient needs and preferences by providing a centralised view on patient demographic information in order to tailor communications and programmes accordingly. PRM introduces the principles of customer relationship management (CRM) into healthcare. It can be a standalone system (e.g. standard CRM solutions), part of a Patient Administration System (PAS) or an ERP system (Enterprise Resource Planning), but it can also be a mix of standalone solutions for individual aspects (e.g. patient questionnaires, direct marketing activities such as mailings etc.)

### **SCHEDULING OF CRITICAL RESOURCES OR FACILITIES SYSTEMS**

Patient scheduling systems coordinate scheduling of all care providers resources for a specific patient (inpatient or outpatient) and identify conflicts with other appointments for the patients or provider resources. It may include staff, critical resources (beds, surgery rooms, etc.), materials (diagnostic equipments) as well as preparation requirements (anesthesia consultation). It is rarely a stand-alone system and is mainly part of a Patient Administration System (PAS). It may also be part of an Enterprise Resource Planning (ERP) system including features which support clinical and enterprise scheduling. Patient scheduling systems are general and therefore differ from specialised scheduling systems such as Emergency/Operating Room/ICU scheduling systems. They also differ from resource planning or departmental scheduling.

## PART 4: CLINICAL INFORMATION SYSTEMS (CIS)

Clinical Information Systems refer to comprehensive, integrated information systems designed to manage the clinical functions of a hospital.

Clinical Information Systems aim to increase the efficiency of healthcare delivery by archiving patient data, providing faster access to patient data between healthcare professionals/hospital departments and guiding healthcare professionals when making medical decisions.

Clinical Information Systems can be composed of one or more software components with core functions such as electronic patient record information systems, medical document management information systems, computerised physician order entry as well as a large variety of sub-systems in medical specialties (e.g. oncology information systems, orthopedic information systems, etc.) and service departments (e.g. Laboratory Information System, Radiology Information System).

Clinical Information Systems include clinical knowledge and decision support systems, clinical order communication management systems, medical record systems, medico-technical service department systems.

### 4.1. CLINICAL KNOWLEDGE, DECISION & PROCESS SUPPORT INFORMATION SYSTEMS

Systems designed to assist health professionals with decision-making by linking dynamic individual patient health observations with a common clinical knowledge management system. They include among others clinical decision support systems, clinical workflow management systems etc.

#### CLINICAL KNOWLEDGE MANAGEMENT & CLINICAL DECISION SUPPORT SYSTEMS (CDSS)

Clinical Decision Support Systems are an interactive computer programme designed to assist doctors and other healthcare professionals with decision-making tasks by linking dynamic individual patient health observations (e.g. monitored in an Electronic Patient Record) with a common clinical knowledge management system (e.g. a set of rules derived from experts and evidence-based medicine). Decision support systems are based on knowledge management systems also named Rules Engines. Rules Engines maintain complex rule sets designed by end-users and acquired from extra knowledge sources. Rules Engines are critical to extending Electronic Patient Record systems beyond the capabilities of human cognition and enhancing collaboration. Because medical knowledge has moved beyond the ability of unassisted human to track all relevant information, the use of clinical decision support implemented in a Rules Enging is now necessary to practice state-of-the art medicine.

#### CLINICAL WORKFLOW MANAGEMENT INFORMATION SYSTEMS (CWMS)

Clinical Workflow Management Information Systems optimally coordinate the multidisciplinary clinical processes from admission to discharge for each patient based on a single individual care plan by linking a complete view of the patient's movement through the hospital to clinical decision support. It involves the use of workflow engines which support explicit clinical and operational workflows created by users and supported by scientific literature using graphical design tools. It supports the practice of evidence-based medicine and provides the infrastructure necessary for an organisation to optimise its clinical activities. These systems can be standalone solutions from basic Therapy Planning software to departmental solutions integrated with the different clinical information solutions or ultimately integrated solution with Knowledge Management Systems and Decision Support Systems in an Hospital Information Systems/Clinical Information Systems (HIS/CIS).

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### **DISEASE MANAGEMENT INFORMATION SYSTEM**

Disease Management Information System support healthcare professionals to manage patients who have one or more chronic conditions. Such systems, unlike Electronic Patient Records, do not document the entire patient's encounter, but rather focus on chronic disease and preventive care. The use and concept behind Disease Management Information Systems are not widespread, hence relatively new with unclear boundaries. They might often be confused with "disease-specific registry".

### **eLEARNING APPLICATIONS AND ONLINE TRAINING OF STAFF**

eLearning enables the distribution and presentation of teaching materials for professional education and training. eLearning can be based on a range of technologies and media (generally all digital media, here defined as computer and web-based) and covers a broad range of forms and applications.

## **4.2. CLINICAL ORDER COMMUNICATION MANAGEMENT INFORMATION SYSTEMS**

Systems designed to place and share clinical orders between healthcare professionals and hospital departments.

### **CLINICAL ORDER ENTRY & RESULT REPORTING/COMPUTERISED PHYSICIAN ORDER ENTRY (CPOE)**

Clinical Order Entry/Results Reporting information systems allow for the placement of clinical service orders for patient services or medications, including medications, procedures, examinations, nursing care, diets, laboratory tests, etc. with subsequent automated distribution of the clinical documentation processed as a result of this order. Order entry and result reporting can be a standalone solution or part of RIS, LIS or HIS. CPOE systems have the same functionality as a Clinical Order Entry/results reporting IS but in addition include special electronic signature, workflow, and rules engine functions.

### **ELECTRONIC TRANSMISSION OF PRESCRIPTIONS INFORMATION SYSTEM (ETP)**

Electronic Transcription of Prescriptions Information System (ETP IS) facilitates the end-to-end medication management including ordering, dispensing and administration. They are point-to-point systems and do not include decision support functionalities. ETP IS can be a standalone solution or a module of Pharmacy information system.

### **ePRESCRIBING SYSTEM**

ePrescribing Systems facilitate the end-to-end medication management including ordering, dispensing, and administration. Compared to the ETP, it goes further and updates the Medication Administration Record. It addresses large-scale benefits of decision support allowing physicians to review patient history and recommended dosage. Very often, it works in conjunction with other technologies, such as mobile devices, bar coding and automated dispensing machines. ePrescribing can be stand-alone solutions or modules of Pharmacy Information Systems.

## **4.3. MEDICAL RECORDS / ELECTRONIC PATIENT RECORD INFORMATION SYSTEMS**

Systems that record and/or host information about the patient on an electronic file. They include digital dictation and transcription information systems, electronic patient records and medical document management systems.



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### **DIGITAL DICTATION & TRANSCRIPTION INFORMATION SYSTEM**

A Digital Dictation Information System facilitates the management of voice-recorded notes and reports. It converts voice-recorded notes and reports as dictated by physicians and/or other healthcare professionals into computerised text format (i.e. Medical Transcription). It can be standalone digital sound recording software and speech recognition software or integrated digital dictation and transcription workflow software.

### **ELECTRONIC PATIENT RECORD (EPR)/ELECTRONIC MEDICAL RECORD (EMR)**

Electronic Patient Record (EPR), Electronic Medical Record (EMR), Computerised Patient Record (CPR) are synonymous. They refer to an individual patient's medical record in digital format generated and maintained in a healthcare institution, such as a hospital or a physician's office (as opposed to a personal health record – PHR – that is generated and maintained by an individual). Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, and billing information.

The purpose of an EPR/EMR can be understood as a complete record of patient encounters that allows the automation and streamlining of the workflow in healthcare settings and increases safety through evidence-based decision support, quality management, and outcomes reporting. EPR/EMR are made up of electronic medical records from many locations and/or sources and a variety of healthcare-related information to enable complete patient-centered documentation from initial diagnosis and therapy through to continuity-of-care planning. A graphical user interface on the clinical workstations allows authorised healthcare providers to retrieve/access, review and update a single patient's record at any linked department or facility. Medical technical devices may feed data automatically into the patient record. EPR/EMR are included in an application environment which is composed of the clinical data repository, clinical decision support, controlled medical vocabulary, order entry and results reporting/CPOE and clinical documentation applications.

### **MEDICAL DOCUMENT MANAGEMENT INFORMATION SYSTEM (MDM)**

Medical Document Management systems mean a central repository system for disparate electronic/digital medical patient documents/files (e.g. care episodes, test results, diagnoses, referrals, discharge letters etc.) Documents may have been digitised (e.g. scanned) or created in digital format (e.g. by information systems). Key functions of medical document management systems include computer-aided document/file entry, indexing, administration, storage and access/retrieval of individual documents/files. Some systems include image archiving functions. Medical document Management systems might be integrated in a Hospital information system/Clinical information system (HIS/CIS).

## **4.4. MEDICO-TECHNICAL SERVICE DEPARTMENT SYSTEMS**

Specialised systems designed to support clinical processes in the various service departments of a hospital. They include – amongst others – laboratory information systems, radiology information systems and picture archiving communications systems.

### **ADVANCED VISUALISATION INFORMATION SYSTEM**

Advanced Visualisation Information Systems (IS) or advanced image processing tools, e.g. 3D MPR/MPI, CT/MR matching, Computer Aided Decision (CAD) support the decision-making processes and visualisation of the areas of interest for physicians in radiology, cardiology, oncology, neurology, pathology, orthopedics etc. Advanced Visualization Information Systems may imply a variety of techniques and methods such as extracting more information from existing datasets, providing a richer display of anatomic information than conventional section, volumetric interpretation of image data, Computer Aided Decision (CAD) and other advanced imaging techniques.

### **CARDIOLOGY PACS**

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Cardiology Picture Archiving and Communications Systems (PACS) are defined as a coherent system including a networked digital archive with online and nearline storage components, dedicated reading workstations, and all the associated software required to store, manage and view cardiology images. As for radiology, Cardiology PACS and Cardiovascular Information Systems (CVIS), the two systems are continuously becoming more integrated.

### **CARDIOVASCULAR INFORMATION SYSTEM (CVIS)**

Cardiovascular Information Systems (CVIS) automate processes within the cardiology department, supporting scheduling, ordering, documentation and data capture. CVIS can be standalone solutions or integrated with a Cardiology Picture Archiving and Communications Systems (PACS) or as a module of a HIS/CIS (Hospital Information System/Clinical Information System).

### **ELECTRONIC HEALTH RECORD (EHR)**

An Electronic Health Record (EHR) is a record in digital format containing medical information about a patient. Such records may include a whole range of data in comprehensive or summary form, including demographics, medical history, medication and allergies, immunisation status, laboratory test results, radiology images, vital signs, personal statistics like age and weight and billing information.

### **EMERGENCY INFORMATION SYSTEM**

Emergency Information Systems support emergency department clinicians, nurses and staff in the critical task of managing patients quickly and efficiently. They provide features for care management and instant access to up-to-date patient information. They ensure a smooth transition for patients including triage and tracking as they are admitted to hospitals or discharged. Emergency IS can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

### **IMAGING DATA CENTERS (IDC)**

Imaging Data Centers (IDC) provide a central imaging data repository (in-house or off-site) for a multi-site environment (e.g. a hospital chain), region or country. Very often based on a hub and spoke model, IDC provide a redundant central data repository to store and archive radiology and non-radiology diagnostic images often including relevant key image notes/post processing measurements combined with relevant reports. Outside the sharing of information based on secure access and authorisation, IDC offer resilience against network interruptions, centralised long-term archive and disaster recovery services.

### **INTENSIVE CARE UNIT INFORMATION SYSTEM (ICU IS)**

Intensive Care Unit Information Systems provide automated functions for the automated documentation and protocol intervention management by the intensive care unit. Intensive care unit information systems also capture the data output from all medical devices monitoring the patient's clinical status. They include order entry, clinical documentation and flow charts, decision support and results reporting. They often summarise large amounts of observations to feed into the electronic medical records. ICU IS can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

### **INTERNAL MEDICINE INFORMATION SYSTEM**

Internal Medicine Information Systems provide automated functions in the internal medicine department. Internal medicine Information Systems can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

### **LABORATORY INFORMATION SYSTEM (LIS OR LIMS)**

Laboratory Information Systems (LIS) provide complete support for the laboratory department from an operational, clinical and management perspective. LIS can cover a number of different laboratory or pathology systems including different specialties such as Hematology, Histopathology, Microbiology, etc. The system provides an automatic interface to laboratory analytical instruments to transfer verified results to nurses' stations and even to remote doctors' offices. The system allows the user to receive orders from any designated location, process the order and report results, and maintain technical, statistical and account information.

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Laboratory Information Systems are available as standalone solutions or as module(s) of Hospital Information Systems/Clinical Information Systems (HIS/CIS).

#### **NURSING INFORMATION SYSTEM**

Nursing Information Systems document nursing notes which describe the nursing care or services provided to a patient. It provides observations, decisions, actions and the outcomes of these actions. Nursing Information Systems track what occurred and when it occurred. They can be standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

#### **ONCOLOGY INFORMATION SYSTEM**

Oncology Information Systems comprise a set of systems which manage advanced clinical, administrative and financial processes in a completely integrative environment. Oncology Information Systems automate the clinical decision-making and complex communications needs of the medical oncology care team. It provides the ability to share information across venues for complex, multi-encounter chemotherapy protocol management. Oncology Information Systems can be a standalone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

#### **OPERATING THEATRE IS (OT IS)**

Operating Theatre Information Systems provide automated functions in the operating theatre department. OT IS can include peri-operative, post-operative and pre-operative functionalities. They might also include OT scheduling functionalities. OT IS can be stand-alone solutions or modules of a Hospital Information System/Clinical Information System (HIS/CIS).

#### **ORTHOPAEDICS INFORMATION SYSTEM**

Orthopaedics Information Systems provide automated functions in the Orthopaedics department. When associated with a PACS, they include image acquisition, storage, distribution and viewing to preoperative planning using digital implant templates. Orthopaedics Information Systems can be standalone solutions or modules of Hospital Information System/Clinical Information System (HIS/CIS).

#### **PHARMACY INFORMATION SYSTEM (PHIS)**

Pharmacy Information Systems provide complete support for the pharmacy department from an operational, clinical and management perspective. It also allows the pharmacist to enter and fill physician orders, and as a by-product, performs all the related functions of patient charging, distribution of drugs and re-supply scheduling, pharmacy stock control, tracking of usage at ward level and post-hoc checking of prescriptions. PHIS may be associated with CPOE for prescriptions (CPOE or ePrescribing). PHIS can be standalone solutions or modules of Hospital Information Systems/Clinical Information Systems (HIS/CIS). Patient safety imperatives are driving a trend to tighter and tighter integration within HIS/CIS.

#### **RADIOLOGY INFORMATION SYSTEM (RIS)**

Radiology Information Systems are used by radiology departments to store, manipulate and distribute patient radiological data and imagery. The system generally consists of patient administration, scheduling, examination, reporting, accounting, statistics and system administration. The RIS can be standalone or integrated in a Picture Archiving and Communication System (PACS) or the Hospital Information System (HIS).

#### **RADIOLOGY PACS**

Radiology Picture Archiving and Communications Systems (PACS) address providers' storage, retrieval, distribution and presentation requirements for radiography imaging. While older PACS implementations do not include Radiology Information Systems (RIS), the two systems are becoming ever more integrated, moving away from standalone systems and towards combined PACS and RIS. While Radiology PACS has traditionally been located within the radiology department, the importance of these systems to other clinical areas, including cardiology and pathology, continues to grow. PACS can be available as standalone solutions (modality

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PACS – basic solution integrated with the imaging device; mini-PACS – scaled-down/entry-level departmental solution), hospital-wide general or speciality, (e.g. Radiology PACS) or integrated RIS/PACS.

### **TELERADIOLOGY INFORMATION SYSTEM**

Teleradiology Information Systems enable the secure remote evaluation of digital diagnostic studies (CT scans, MRIs and X-Rays). This technology enables both remote staff radiologists and third-party providers to complete primary and non-primary diagnostic studies from any location. It includes hospital-to-home teleradiology for out-of-hours health care coverage e.g. remote working for radiologists who are part of the hospital radiology department. It also covers outsourcing to other imaging centres or commercial teleradiology companies that provide outsourcing services for image interpretation (night and/or day reads).

### **VENDOR NEUTRAL ARCHIVING (VNA)**

A VNA provides image storage, management, archiving and routing functions for one or more medical imaging documentation and archiving systems. It may also include integration to a clinical viewer offering secure access to standard imaging data from existing workstations anywhere on the network. The viewer is generally considered an external component to the VNA.

## GENERAL INFORMATION ABOUT COCIR

Founded as a non-profit trade association in 1959, COCIR represents the radiological, electromedical and healthcare IT industry in Europe. As such, our members play a driving role in developing the future of healthcare both in Europe and worldwide.

COCIR is committed to supporting its members and communicating with its partners in Europe and beyond on issues which affect the medical technology sector and the health of EU citizens.

COCIR also works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems without compromising the safety of patients and users.

We encourage the use of advanced technology to support healthcare delivery worldwide.

COCIR's key objectives include promoting free worldwide trade of medical devices and maintaining the competitiveness of the European health sector.

## COCIR COMPANY MEMBERS:



## NATIONAL TRADE ASSOCIATIONS MEMBERS:



### COCIR HOW TO JOIN US

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