Big data analysis in health care and the General Data Protection Regulation

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Outline

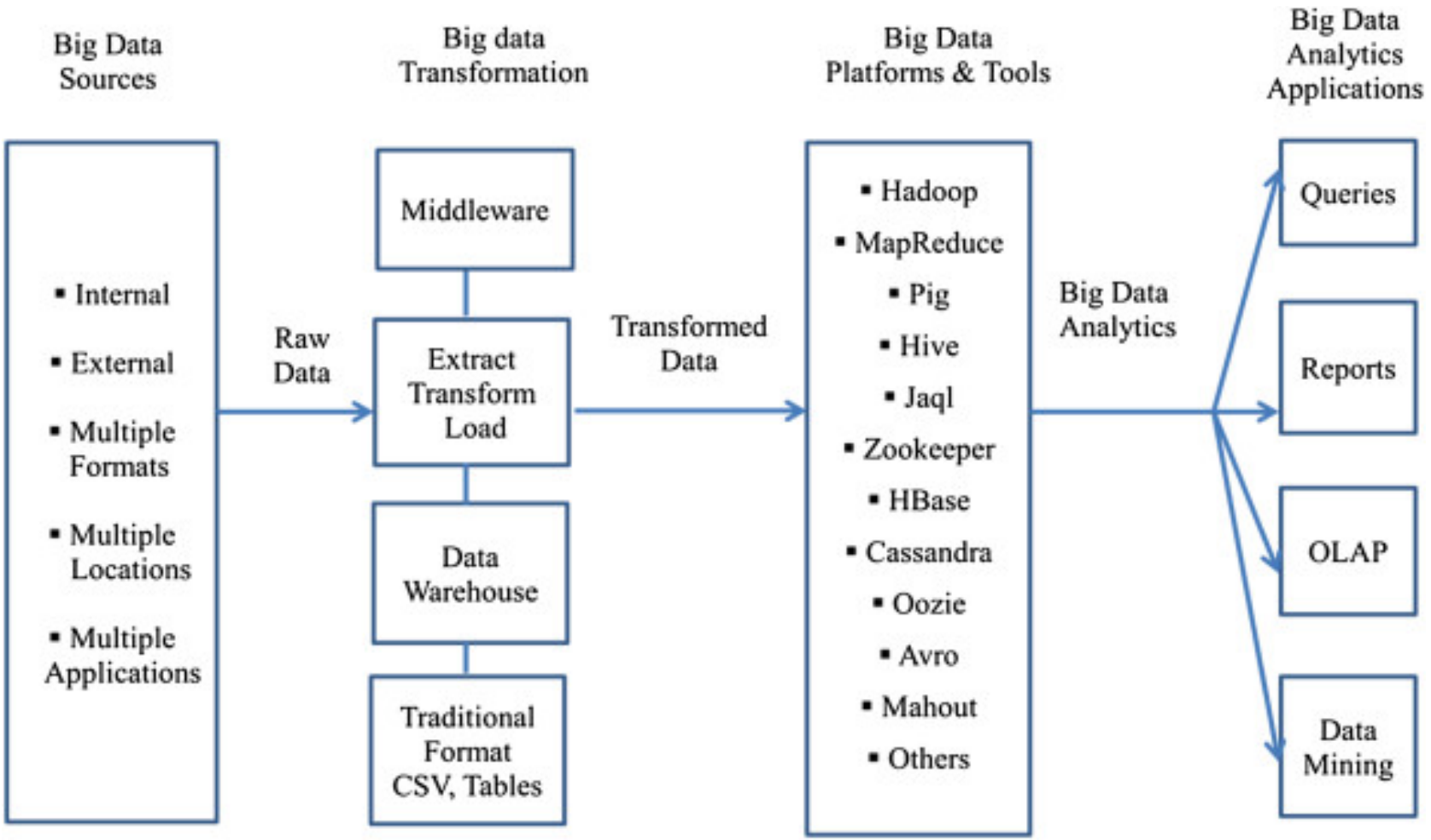
- Big data analysis
  - some characteristics
  - components
  - value chain
  - some areas in health care
- EU General Data Protection Regulation (GDPR)
  - principles
  - methodology
- The main challenge
  - how to use the opportunities of big data analysis in health care
  - while effectively managing the risks
- Implementation in Belgium: possible support by
  - the eHealth platform
  - the HealtData.be platform

Some characteristics of big data analysis

- Data characteristics
  - high volume, variety, velocity, veracity
  - multiple data sources
  - data collection too large and/or too complex to be treated by traditional software

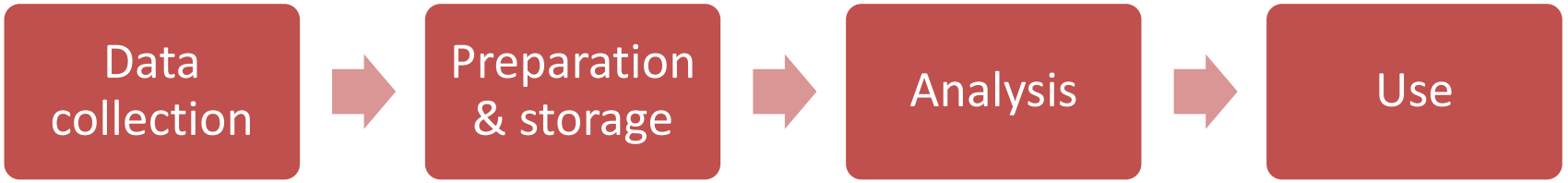
- Characteristics of methods/techniques to analyse data
  - data driven, looking for patterns and correlations
  - rather than hypothesis driven, looking for causalities

Big data analysis components



Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4341817/

Big data analysis value chain



- Iterative, rather than sequential process
- Use of data can be
  - descriptive
  - predictive
  - prescriptive
- Need for appropriate measures to mitigate risks
  - in all phases
  - taking into account the type of use

Big data analysis areas in health care

- Support of clinical operations
  - comparative effectiveness research to determine more clinically relevant and cost-effective ways to diagnose and treat patients
- R&D
  - predictive modeling to and produce a leaner, faster, more targeted R&D pipeline in drugs and devices
  - statistical tools to improve clinical trial design and patient recruitment
  - analyzing clinical trials and patient records to identify follow-on indications and discover adverse effects before products reach the market

Source: McKinsey

Big data analysis areas in health care

- Public health
  - analyzing disease patterns and tracking disease outbreaks and transmission
  - faster development of more accurately targeted vaccines
  - turning large amounts of data into actionable information that can be used to
    - identify needs
    - provide services
    - predict and prevent crises

Source: McKinsey

Big data analysis areas in health care

- Contribution to
  - evidence-based medicine
  - genomic analytics
  - pre-adjudication fraud analysis
  - device/remote monitoring
  - patient profile analytics to identify individuals who would benefit from preventive care or lifestyle changes

Source: McKinsey

EU General Data Protection Regulation

- Main principles
  - purpose limitation
  - proportionality
  - accuracy and data quality
  - security
  - transparancy
  - accountability
- Methodology
  - risk based approach
  - documentation duty
  - privacy by design
  - privacy by default
  - codes of conduct
  - certification
  - additional measures for sensitive data

Some risks and how to manage them

- Risk of singling out individuals without necessity
  - aggregation, anonymisation and pseudonymisation of data
  - small cells risk analysis
  - legal obligation to not to attempt to re-identify data subjects

- Risk of data bias
  - careful selection of data used
  - reliable analysis methodologies (interative modelling)
  - ‘equal opportunity by design’
  - appropriate training
  - transparancy

Some risks and how to manage them

- Risk of violation of purpose limitation principle
  - preliminary transparency about purposes of big data analysis
  - respecting GDPR, especially in case of big data analysis for public health or scientific research purposes

- Risk of huge increase of data storage (quantity and duration)
  - limitation of personal data storage to the extent and during the time useful for the foreseen legitimate purposes
  - aggregation, anonymisation or pseudonymisation of personal data that are only stored for public health or scientific research purposes

Mission of the eHealth platform

- How?
  - through a well-organised, mutual electronic service and information exchange between all actors in health care
  - by providing the necessary guarantees with regard to information security, privacy protection and professional secrecy

- What?
  - optimisation of health care quality and continuity
  - optimisation of patient safety
  - reduction of administrative burden for all actors in health care
  - thorough support of health care policy and research

10 Tasks of the eHealth platform

- Development of a vision and of a strategy for eHealth
- Organization of the cooperation between all governmental institutions which are charged with the coordination of the electronic service provision
- The motor of the necessary changes for the implementation of the vision and the strategy with regard to eHealth
- Determination of functional and technical norms, standards, specifications and basic architecture with regard to ICT

10 Tasks of the eHealth platform

- Registration of software for the management of electronic patient files

- Managing and coordinating the ICT aspects of data exchange within the framework of the electronic patient files and of the electronic medical prescriptions

- Conceptualization, design and management of a cooperation platform for secure electronic data exchange with the relevant basic service

10 Tasks of the eHealth platform

- Reaching an agreement about division of tasks and about the quality standards and checking that the quality standards are being fulfilled

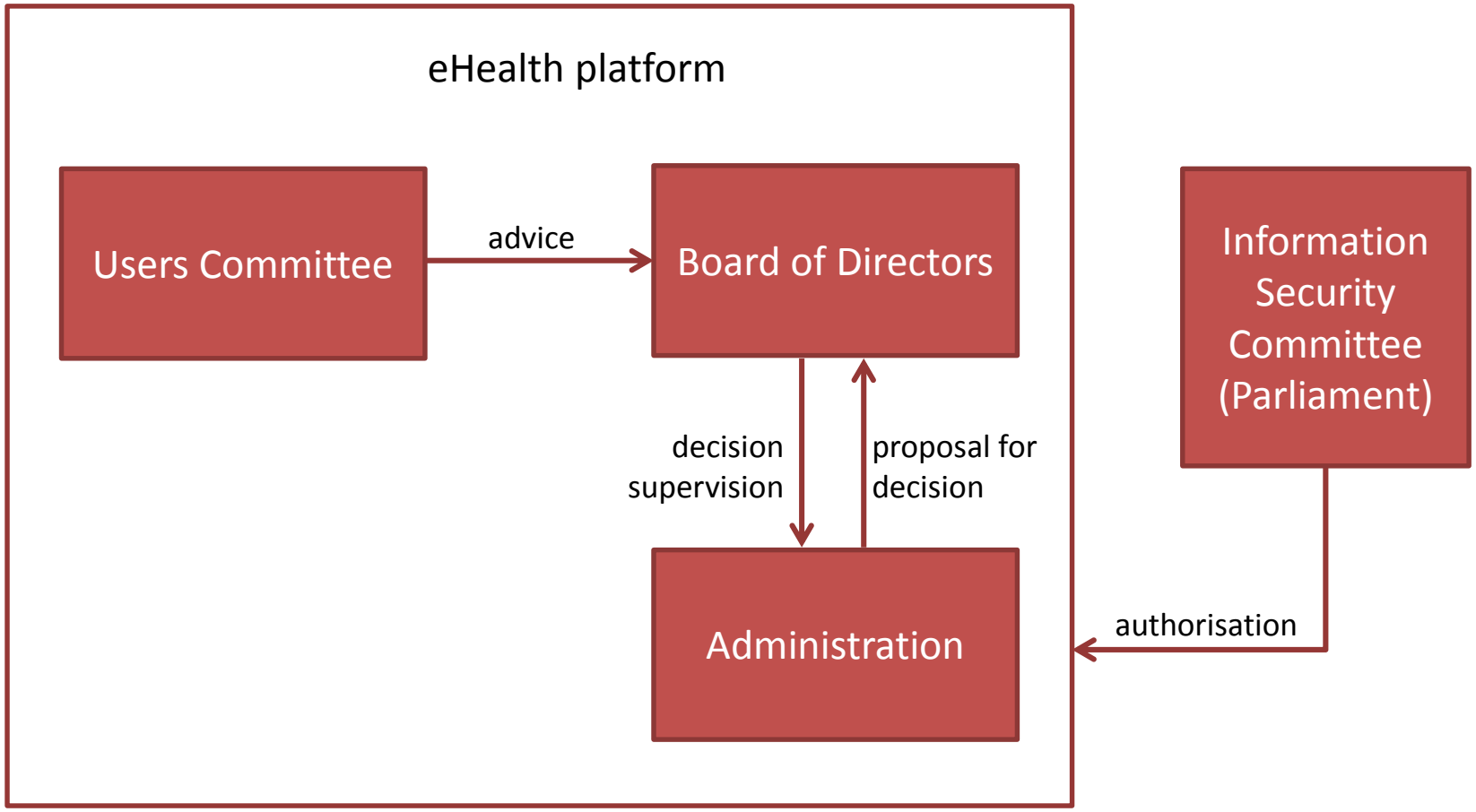
- Acting as an independent trusted third party (TTP) for the encoding and anonymisation of personal information regarding health for certain institutions summarized in the law for the support of scientific research and the policymaking

- Promoting and coordinating programmes and projects

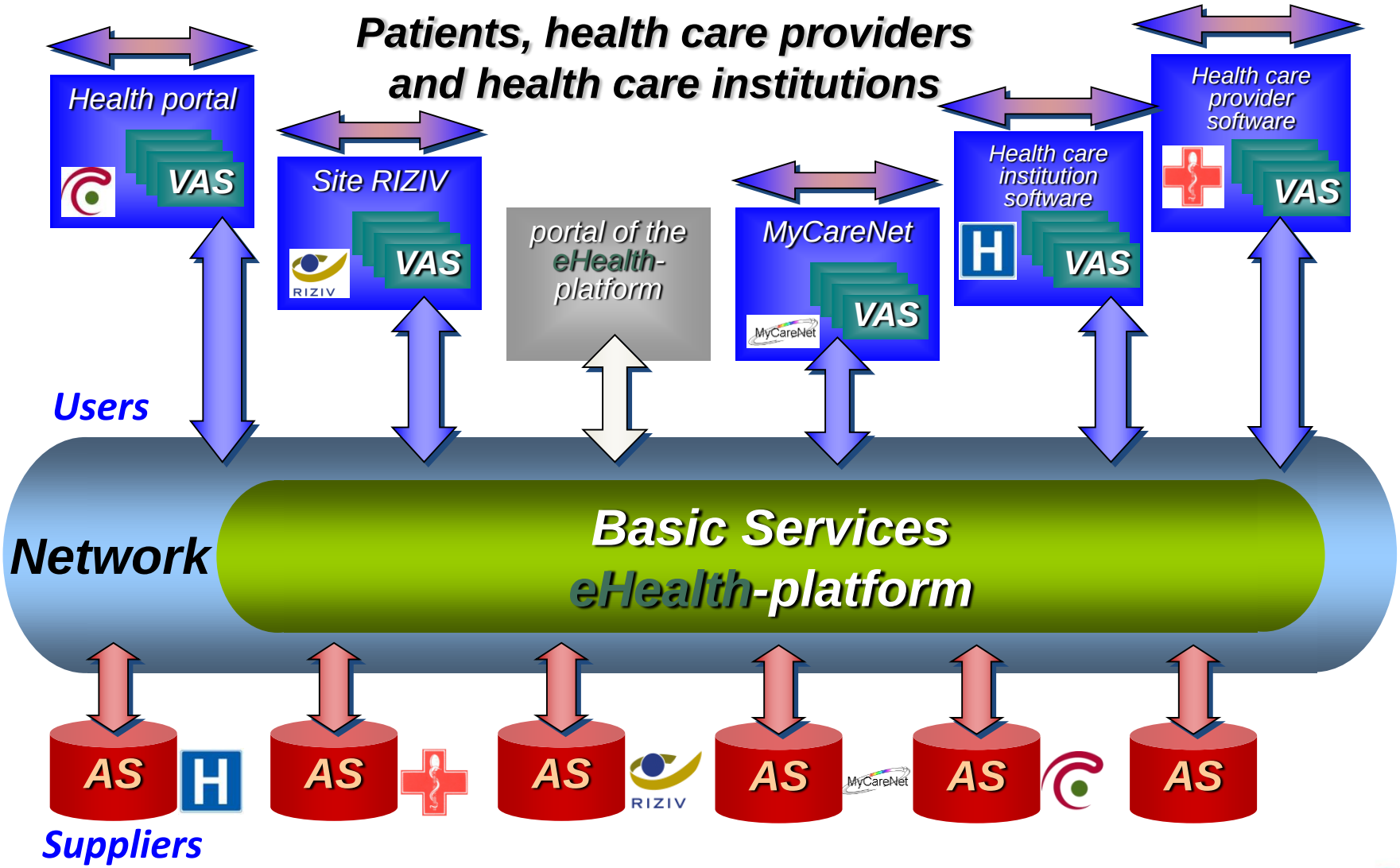
Possible support by eHealth platform

- Stakeholder involvement
  - Board of Directors
  - Users Committee
- Organisational and technical support
  - proposals for policies and codes of conduct
  - trusted third party for anonymisation and pseudonymisation of data (separation of duties)
  - organisation of small cells risk analysis
- Independent Information Security Committee designated by Parliament
  - approval of policies and codes of conduct
  - authorisation for data exchange => preventive measures

Governance of the eHealth platform



eHealth platform: basic architecture



eHealth platform: 10 basic services

- Coordination of electronic sub-processes
- Portal
- Integrated user and access management
- Logging management
- System for end-to-end encryption
- eHealthBox
- Timestamping
- Encoding and anonymization
- Consultation of the National Identification Registers
- Reference directory (metahub)

What the eHealth platform does NOT

- Collecting personal health data
- Storing personal health data
- Storing anonymized or pseudonomized health data
- Analysing health data
- Carrying out studies

Possible support by Healthdata.be platform

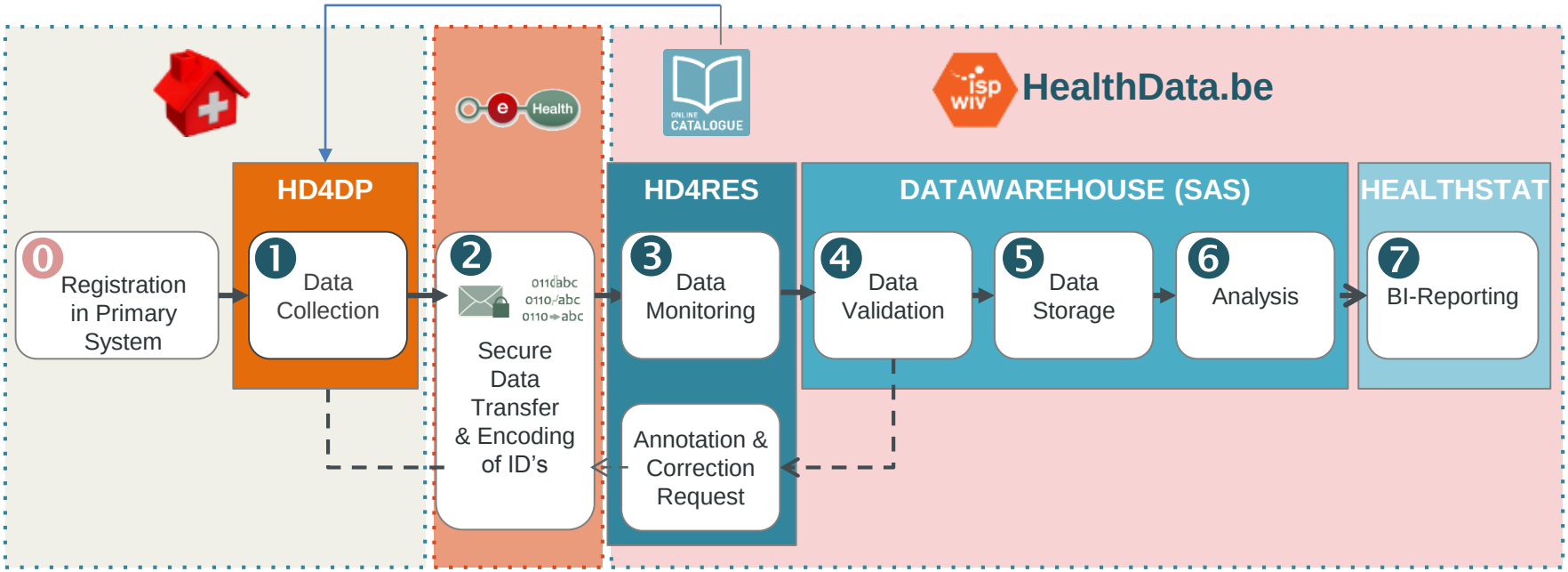
- Public service by Sciensano (formerly known as WIV-ISP)
- Objective: re-use of digitalized information from clinical workflow (real world), and ,preferably, from authentic sources or other validated databases (linked data) for research
- Approach
  - one technical architecture (free & open)
  - one information architecture (independent from technical implementation)
  - one set of business processes

The healthdata.be platform

- Ambition: no administrative burden, higher efficiency, should result in
  - more time for patient and thus higher quality of care
  - more time for research and thus higher quality of research
  - lower overall costs
- Guiding scientific principles of the Healthdata.be platform: the FAIR principles (cf Wilkinson et al. 2016): data and metadata should be
  - Findable
  - Accessible
  - Interoperable
  - Re-usable

Healthdata.be architecture

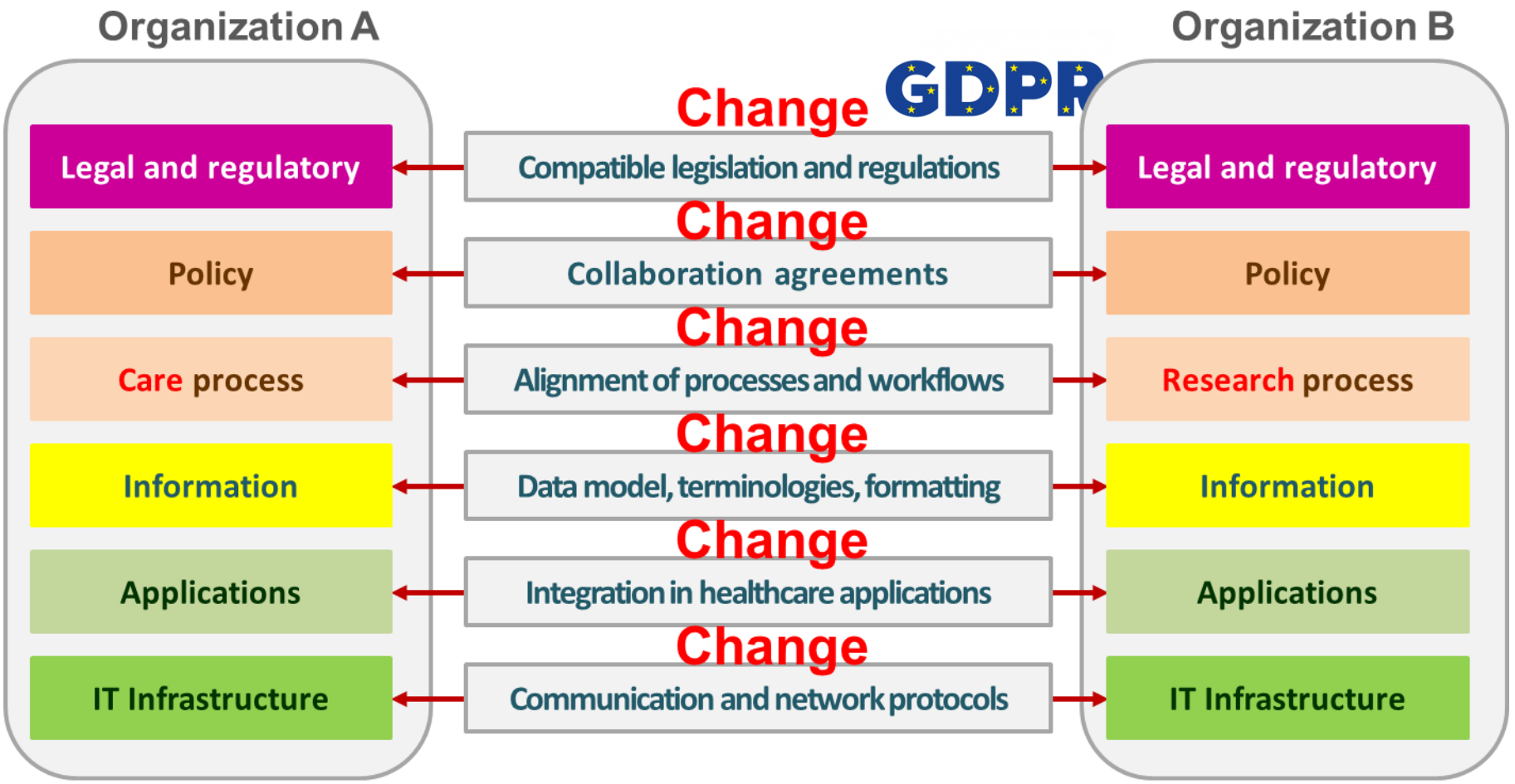
- One generic technical architecture for collection and management of real world data is in production in all Belgian hospitals and most laboratories



The healthdata.be platform

- Architecture of healthdata.be was thoroughly evaluated:
  - positive advice from Working Group Architecture of Users Committee
  - authorisation from Information Security Committee
  - approval from eHealth platform
- 25 scientific projects are in production; more then 100 projects on to do list
- Healthdata.be
  - collects very diverse clinical data: vital signs, diagnoses, procedures, but also complex “Next Generation Sequence data”, and will also collect Patient Reported Outcomes and Patient Reported Experiences
  - collaborates with other data warehouses: e.g. Crossroads Bank for Social Security for research on social impact of diseases and therapies

Key determinant : multidimensional interoperability



Being "technically" able to exchange data is not enough !

Redefined eHealth European Interoperability Framework (2015)

Key determinant: trust

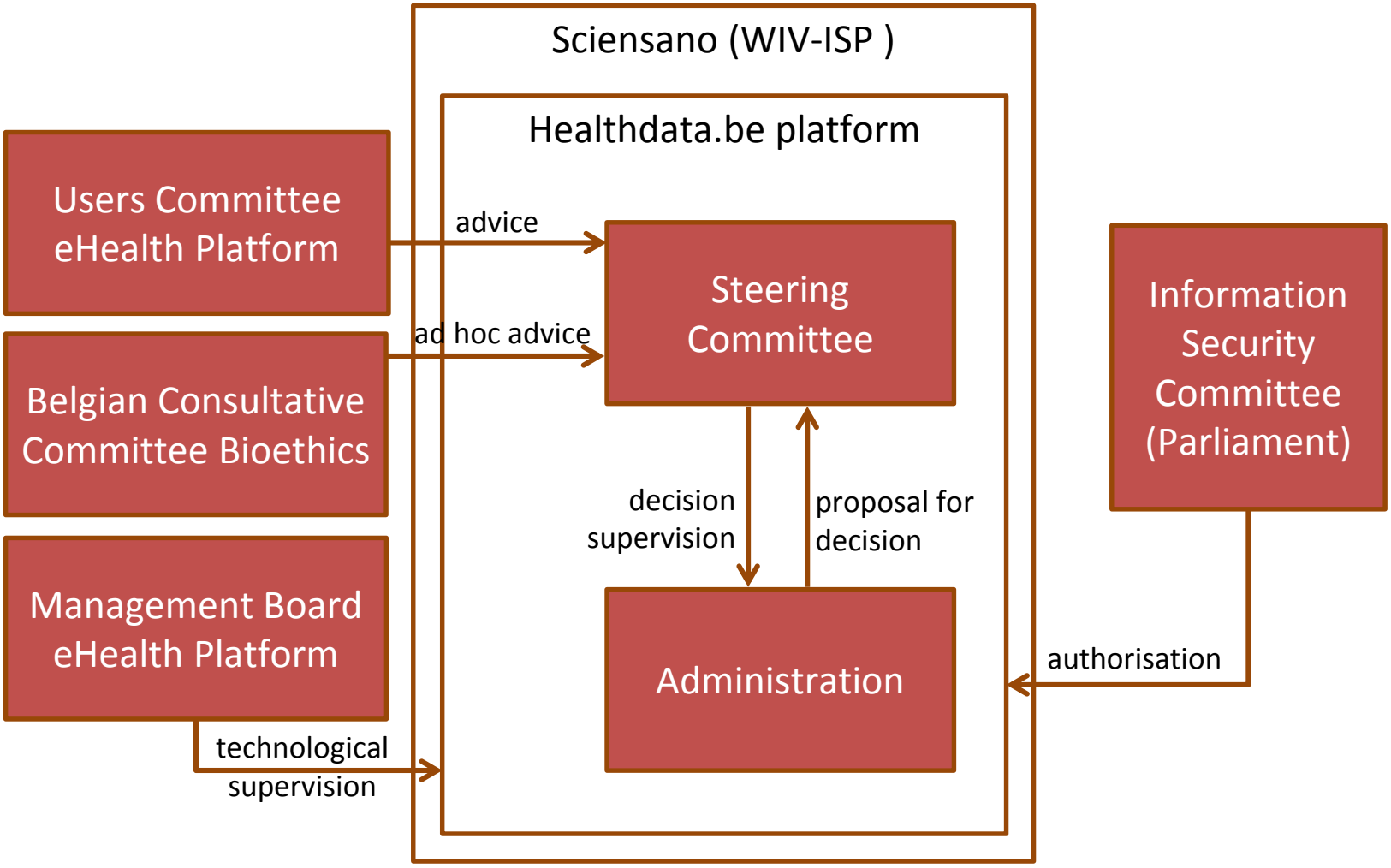
- All scientific projects are - before entering into production - subject to :
  - internal evaluation by responsible physician and Data Protection Officer (DPO)
  - external evaluation by Steering Committee and Information Security Committee

- Collected data becomes available for researchers only after small cell risk analysis by independent specialists, appointed by Information Security Committee

Key determinant: trust

- Privacy by design: use of trusted third party (eHealth Platform) for encryption, pseudonymisation, authentication, …
- Applications and datacenter are under supervision by key stakeholders (care providers, patients, governments, …) represented in Management Board eHealth platform
- Monitoring and auditing: use of software that monitors all activity on infrastructure
- Foreseen migration (2019) towards and thus benefit of security measures and services of VAS G-Cloud were other applications with highly sensitive data function

Governance of Healthdata.be platform



Thank you !
Any questions ?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