

Agence eSanté Luxembourg



Présentation AEHM
4 mai - Luxembourg

Luxembourg, a cosmopolitan country : particularities



~ 570,000 citizens of which 45% foreigners
50% of which: Portuguese
170 different nationalities



3 official languages :
Luxembourgish (national), French, German,
(English widely used business language)

~ 180,000 commuters (FR/BE/GE)



necessity of medical data sharing, also on cross-border level





Luxembourg – Healthcare System

- 5 major hospitals for acute care and 5 hospitals for specialized care,
- ~ 100 public Pharmacies,
- ~ 2200 Doctors,
- Laboratories:
 - 3 private Laboratory groups,
 - 1 national Laboratory (LNS),
 - each hospital has a Laboratory,
- 2 major providers for home care (cover 97%)
- Up to 60 institutions for long term care





a truly cosmopolitan country with a strong political commitment to enhance ICT driven economic and healthcare services development

National eHealth action plan



Mrs Lydia Mutsch – Minister of Health

Launched in 2006 - objectives : improve prevention, drive better diagnosis and treatment and coordinated care of patients, improve the healthcare quality and safety to benefit the patient



Mr Xavier Bettel - Prime Minister

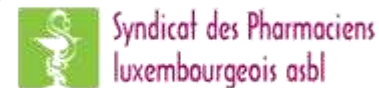
Objective: strengthen and consolidate the country's position in the ICT area and enhance its development as a high tech expert center

Major stakeholders represented in our governing body



LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG

Represented by Ministry of Health and Ministry of Social Security





Our missions as defined by law :

eSanté platform

- Implementation, deployment, operation, and administrative and technical management of a national electronic platform for the exchange and sharing of health data, as well as applications and health information systems at a national level

Interoperability & Security

- Promoting interoperability and security in the implementation of health information systems

Road map

- The establishment and maintenance of a roadmap for health information systems, defining a national strategy, articulated with national health priorities and the need for data exchange and sharing between stakeholders

Orientation

- Assist regulators and authorities on strategic choices related to health information systems

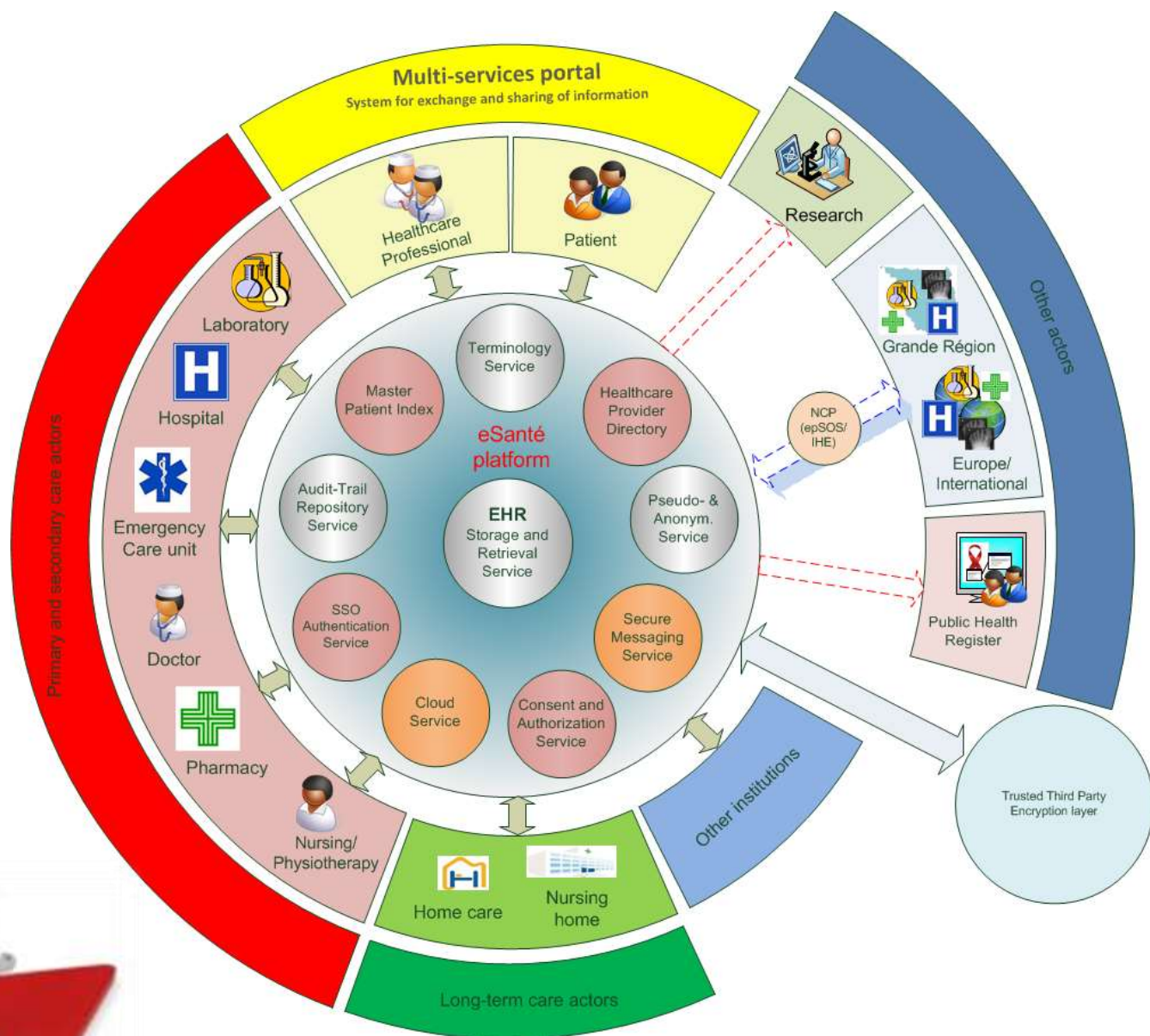
External Communication

- Information for patients and providers on operational procedures and security measures in relation to the electronic health record and the national electronic platform for the exchange and sharing of health data

eSanté Platform :

- **July 2012:** recruitment of the team (5), 18 currently,
- **January 2013 :** launch of European call for tender,
- **January 2014 :** Launch of the Platform's first services.

Accessible via website www.esante.lu, which also serves as Information Portal





Future Challenges :

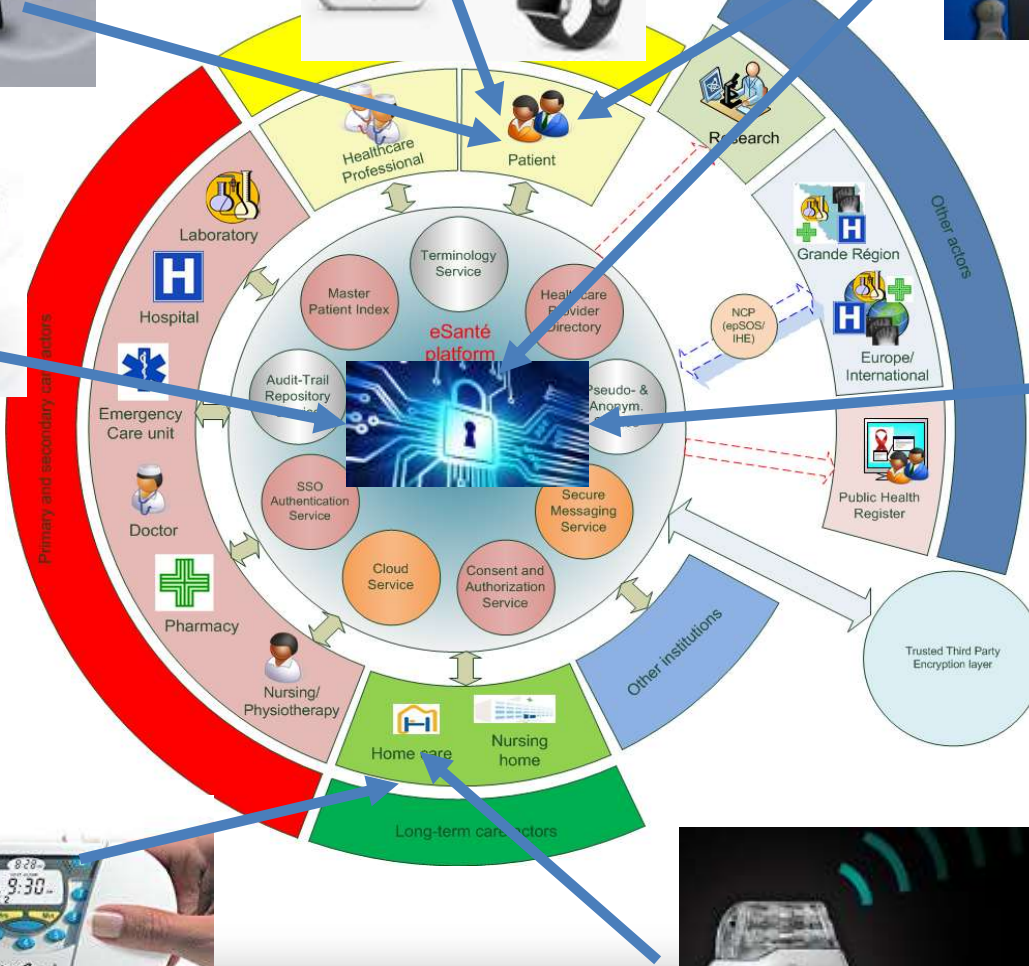
1 – Development and application of artificial intelligence (AI) technologies:

- For big-data processing
- In decision-making in particular in cancer and rare diseases
 - Development of robots or services with a certain level of decision-making autonomy and actions

2 – Mobility in health :

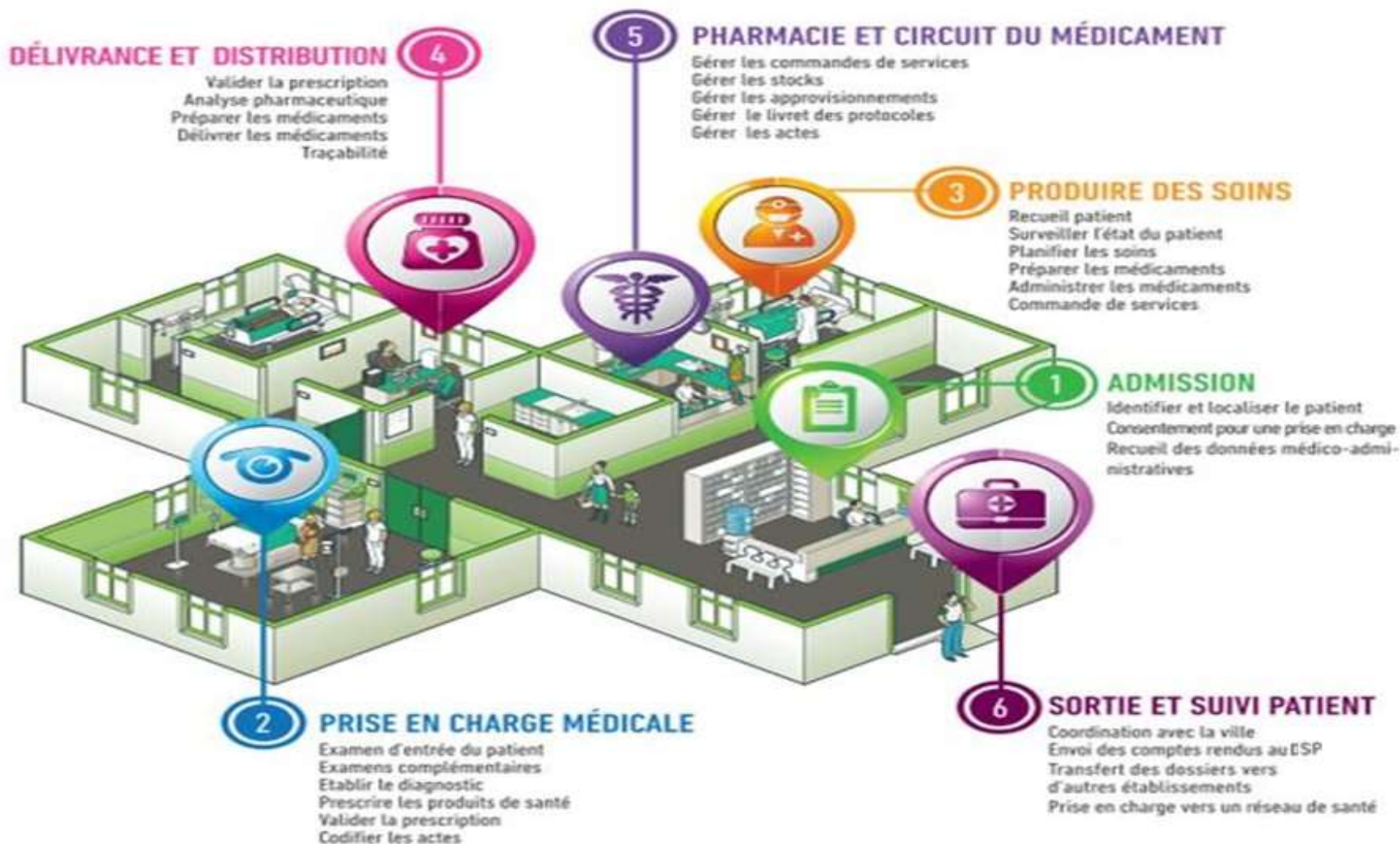
- Reply to a high level of security, particularly in the security chain of data exchange.
- Development and integration of connected devices in the health and care ecosystem.

Connected devices:





Hospital work flow based infrastructure :



Future challenges





GDPR : General Data Protection Regulation

- **Main changes brought about by GDPR – general facts**
 - Field of application reaching beyond EU borders, creation of European Committee for Data Protection and one-stop shop system
 - **Strengthening rights of persons concerned**
 - Expression of consent via a positive explicit act, invalidated by the presence of a derangement, with legal representatives' consent in the case of minors under 16
=> possibility of exemptions under specific conditions in the case of scientific research-oriented treatments and treatment in the interest of the public
 - Right to information via clear and understandable means, right to erasure, right to portability, right to opposition to and restriction of the treatment
 - Representation via an association in case of action or complaint
 - **Privacy by design and Privacy by default mandatory, including organizational aspects through the performance of DPIA, and technical aspects via the application of recognized security measures** (anonymization, encryption, Privacy Enhancing Technologies « PETs »)



GDPR : General Data Protection Regulation

- **Main changes brought about by GDPR – general facts**
 - **Abolition of administrative formalities but strengthening of accountability:**
 - Obligation for the person in charge of the treatment to prove its compliance with GDPR rules (registries and internal controls, good practice manuals, certifications)
 - Appointment of a Data Protection Officer (DPO) for public-sector and high-risk treatments
 - Notification of personal data violation cases to authorities and person concerned
 - **Upgrade of subcontractor's obligations under GDPR (so of accountability) with obligation for subcontractor to prove its compliance as well**
 - **Strengthening penalties:**
 - According to the seriousness of the offense and the level of non-compliance from 2 to 4% of the global sales or from €10 million to 20 million
 - Possibility of criminal penalties defined by country



G.I.E. Agence eSanté Luxembourg

Agence nationale des informations partagées dans le domaine de la santé

Bureaux : 125, route d'Esch L-1471 Luxembourg

Siège social : Villa Louvigny – Allée Marconi L-2120 Luxembourg

RC Luxembourg C-69



Future Challenges : Intégrer dans son ADN le GDPR : General Data Protection Regulation

- **Principaux changements apportés par le GDPR – généralités**

- Champ d'application au-delà des frontières de l'Union Européenne, création du Comité européen à la protection des données, et système de guichet unique
- **Renforcement des droits des personnes concernées**
 - Consentement par un acte positif explicite, non valide en présence de déséquilibre, avec consentement des représentants légaux pour les mineurs de moins de 16 ans
=> possibles dérogations sous conditions pour les traitements à des fins de recherches scientifiques et traitement dans l'intérêt public
 - Droit d'information par des moyens clairs et compréhensibles, droit à l'effacement, droit à la portabilité, droit à l'opposition et la restriction du traitement
 - Représentation par une association en cas de recours, plainte
- **Privacy by design et Privacy by default** obligatoire incluant les aspects organisationnels par la réalisation de DPIA, et les aspects techniques par l'application de mesures de sécurité reconnues (anonymisation, chiffrement, Privacy Enhancing Technologies « PETs »)



- **Principaux changements apportés par le GDPR – généralités**
 - **Suppression des formalités administratives, mais renforcement de l' « accountability » :**
 - Obligation pour le responsable de traitement de prouver sa conformité avec les règles de GDPR (registres et contrôle interne, codes de bonne conduite, certifications)
 - Désignation Délégué à la Protection des Données (DPO) pour les traitements dans le secteur public et pour les traitements à risque
 - Notification de violation de données à caractère personnel à l'autorité et la personne
 - **Augmentation des obligations du sous-traitant dans le respect du GDPR (donc de la responsabilité) qui se doit de prouver sa conformité également**
 - **Renforcement des sanctions :**
 - Selon la gravité de l'infraction et le niveau de non-conformité de 2 à 4 % du Chiffre d'Affaire mondial ou de 10 à 20 10 à 20 millions €
 - Possibles sanctions pénales déterminées par pays