GDPR is good for HL7 and standardisation

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Any information relating to an identified or identifiable natural person

Data may be...

- Named
- Pseudonymised
- Anonymised
Processing health related data is prohibited unless.....

- Data subject has given explicit consent
- Necessary for employment/social security/social protection
- Necessary to protect vital interests of a person
- Necessary for establishment/exercise/defence of legal claim
- Necessary for preventive or occupational medicine, assessment of working capacity, medical diagnosis, healthcare
- Necessary for reasons of public interest in public health
- Necessary for archiving, scientific/historical research or statistical purposes
The data subject has several rights ..... 

- The right to be informed
- The right of access
- The right to rectification
- The right to erase (RTBF)
- The right to data portability
- The right to restrict processing
- The right to object
- Rights in relation to automated decision making and profiling
Personal data breach

Breach of security is anything leading to accidental or unlawful

- Access
- Alteration
- Unauthorised disclosure
- Loss
- Destruction

…. Costs reputation

…. And money

Severe breaches:
- Up to 20 MEUR or 4 % of worldwide annual turnover of the ‘undertaking’, whatever is higher

Other breaches:
- 10 MEUR or 2 %, whatever is higher

Ongoing/multiple infringements:
- Multiples fines likely
But we just make the software / devices, surely the doctors and hospitals are responsible for how they are used .....  

“software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, inter alia, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device, even if such software does not act directly in or on the human body”

December 2017 - Case C-329/16
 Syndicat national de l’industrie des technologies médicales (Snitem), v Premier Ministre, Ministre des Affaires sociales et de la Santé
By 25th May all medical device manufacturers must have implemented the new GDPR rules in the design of their devices, systems and software.

- **Privacy by design** - obligations for both hard and software
- **Documentation of privacy compliance capacity** - purchasers may demand written proof of capacity to meet privacy requirements, to give appropriate information to data subjects and in DPIAs
- **Data Portability** - data subjects have the right to access their data in a structured, commonly used and machine-readable format, to transmit those data to another data controller. That means that your devices and systems must have been (re)designed to accommodate requests for data portability.
Is the European Union creating the right framework, so the most innovative medical devices are employed in the single market?

Yes...because compliance ....
  • Builds confidence in the medtech industry
  • Supports a growing European industry
  • Creates a level playing field for all industry participants

And a confident medtech market ....
  • Helps address the need for sustainability of care in an ageing population
  • Drives patient engagement
  • Optimises personalisation of care
  • Opens new doors in drug discovery
  • Helps track and trace compliance
  • Provides evidence for new pricing models
  • .........
Regulation is good for business!

• General Data Protection Regulation
• Medical Devices Regulation
• In-vitro Diagnostics Regulation
• Network Information Security Directive
• Clinical Trials Regulation
• ePrivacy Regulation
• Health Technology Assessment
• …and the upcoming review of the Consumer Package

But it requires your full engagement and a thorough understanding of the patient as a consumer and a party with rights.
A case in point - European Reference Networks for Rare Disease
What are the ERNs?

ERNs are networks of healthcare providers aiming at improving quality and safety and access to highly specialised healthcare. Focus on patients affected by rare or low prevalence and complex diseases - added value at EU level.

- Scarcity knowledge / need education
- Complexity / high cost

Identified a number of rare diseases areas that for ERNs to cover.

Multidisciplinary approach

The European Commission is providing funding (limited) to support the approved networks throughout the first five years of their existence.

Key criteria

Patient-centered and clinically led

10 members in at least 8 countries

Strong independent assessment

Fulfilment of Network and Member criteria

Endorsement and approval by national authorities
Current status of the ERN’s

- 300 HOSPITALS
- 900 HEALTHCARE UNITS
- THOUSANDS OF PATIENTS HELPED BY 2020
The ERNs operating model

- Software as a Service (SaaS) that enables health professionals to enrol patients using comprehensive data models and share patient data within and across ERNs.
- Virtual communication tools and DICOM viewers to facilitate the interaction between clinicians.
- Reporting tools to empower users to generate reports of interest for administrative and clinical purposes.
- Data sharing based on security standards and a standardised consent form.
The role of ERNs in Research

The ERNs open up future opportunities for:

1. **Patient registration and data generation**: ERNs provide a bridge between patient care and research – more data will be gathered and identification/recruitment of patients for clinical trials will be facilitated.

2. **Development of guidelines of care**: ERNs will set-up care pathways, consensus guidelines, awareness studies, and support continuing medical education.

3. **Clinical development and knowledge generation**: ERNs will help with the identification of biomarkers, and/or the creation of registries and biobanks.
Thank you!

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