Digitalisation and Big Data: implications for the health sector.

Legal and Regulatory Aspects

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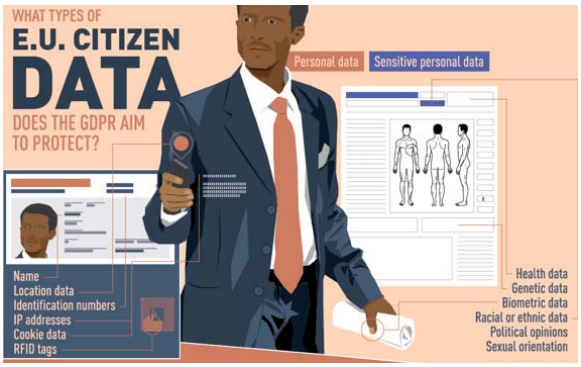
Overview

- On 25 May 2018 new European Union (EU) data privacy legislation, the General Data Protection Regulation (GDPR) came into effect. It replaced the existing national Data Protection laws in EU countries and created (*in theory*) a uniform data protection framework.
- The GDPR hasn't brought manifestly significant approaches to data protection and privacy – organisations in the health sector have always needed to take this subject very seriously – however from an individual's perspective, in enhances their rights around their personal data and places a responsibility on them to understand the reason why their data is being collected, how it's used, shared and secured.
- GDPR (and the many other privacy regulations across the world) requires time, resources and an on-going commitment to ensure you stay on the right side of the regulations – the outcome if you don't, can be severe!

Who does GDPR apply to?



GDPR brings increased accountability

- The GDPR does not prohibit the use of personal data for legitimate purposes, but it does place increased accountability on the organisations using it.
- In today's modern economy, data has become a valuable commodity, and if you are collecting such data you need to instill a culture of being **honest and transparent** about it.
- GDPR brings with it new mandatory breach reporting rules and heavy fines of up to €20m or 4% of a Group's annual worldwide turnover, whichever is higher, for non-compliance and breaches of the regulation.

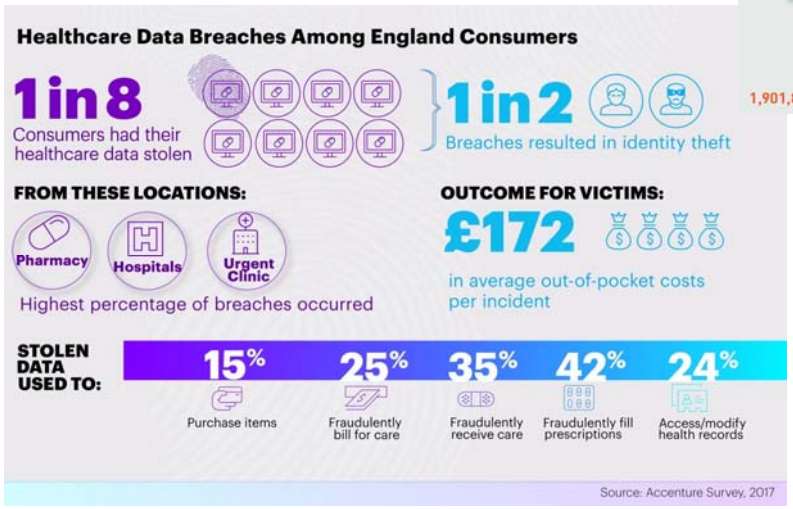
Key health specific challenges

- Are patients interested in a healthier nation?
- Are patients interested in a healthier nation more than they are interested in their own health?
- How do we demonstrate the responsible sharing of their data can lead to better patient outcomes?
- How do we explain the relationship between the three?

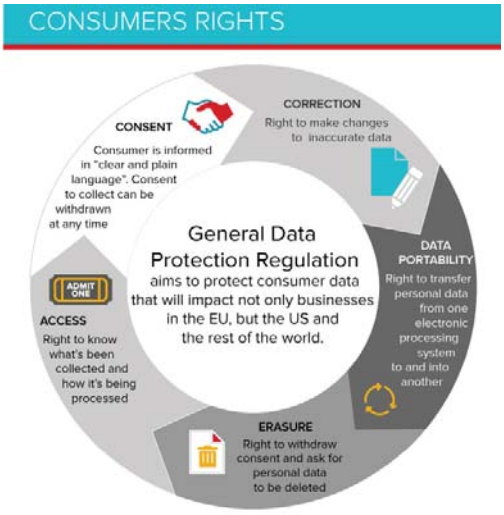
- Where is the balance to be struck between leveraging data for research and clinical purposes to protecting patients rights to privacy?
- Fast moving challenges against the trend – '*Attitudes towards the impact of digitalisation and automation on daily life*' was pre Cambridge Analytica
- **Equitability** of engagement – upper middle class vs working class, impact of age and poverty on access to services

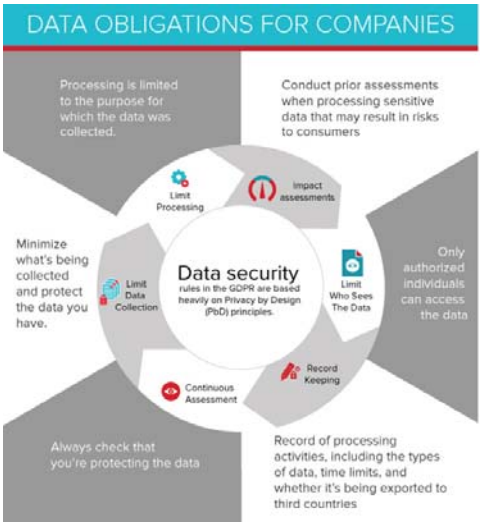
- How do we secure data, when patently we have failed so many times to do so previously
- How do we keep the strategy moving when the risk of failure (in fines, reputation and compensation) is now so great?

Trust and Harm

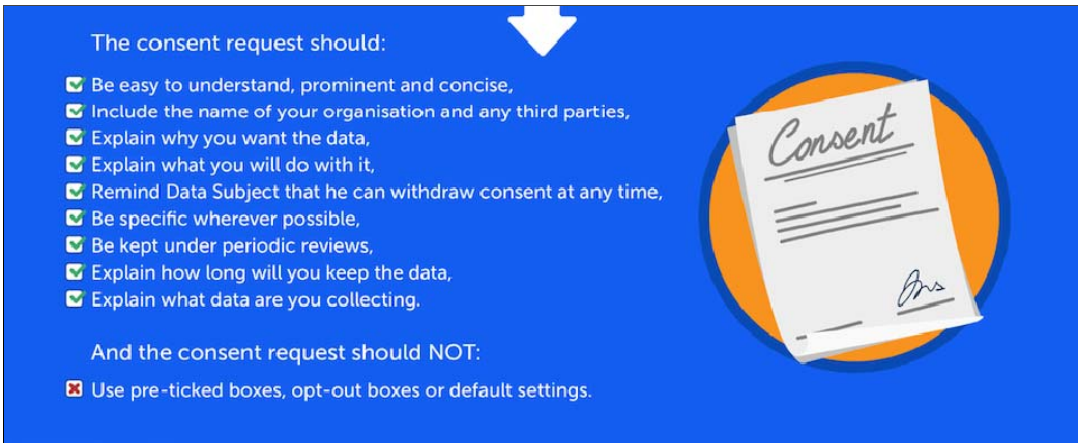


Rights and Obligations

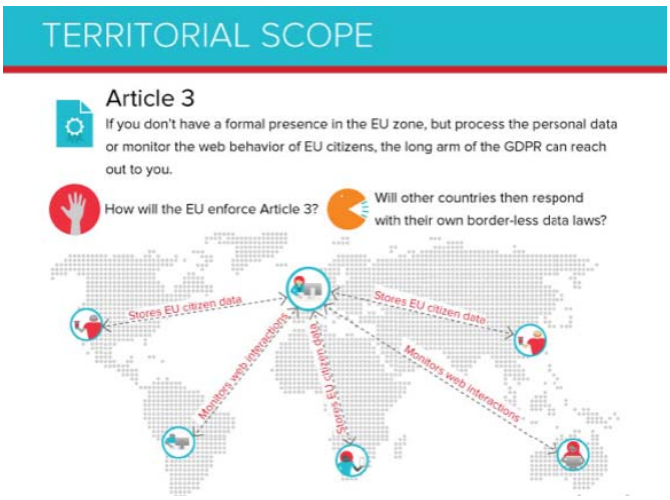


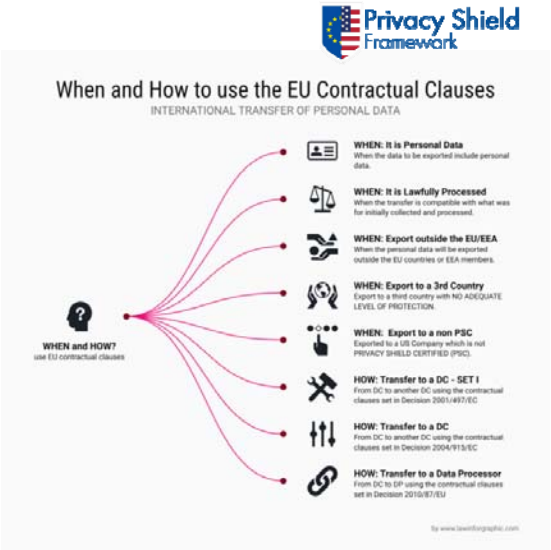


Consent



Trans-Territoriality





View from the Regulators

- Unlike planning for the Y2K deadline, GDPR preparation didn't end on 25th May 2018 – it requires ongoing effort.
- It's an evolutionary process for any organisation – 25 May was the date the legislation took effect, but no organisation stands still. You'll be expected to continue to identify and address **emerging** privacy and security risks in the weeks, months, and years beyond May 2018.
- Key building blocks should be identified:
  - Organizational commitment
  - Understand the information you have
  - Implement accountability measures
  - Ensure appropriate security
  - Train staff