



GDPR Privacy Compliance Update

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Summary

1. Medical Device companies need to consider data protection rights from the beginning stages of product design
 - Accountability of product development is key in the GDPR;
 - One must be ready to ensure compliance at the highest standard and be ready to demonstrate that appropriate safeguards are in place.
2. How to use sensitive data within the Medical ecosystem
 - Medical environment captures very sensitive personal health data;
 - The general rule in Europe is that data related to health cannot be processed in principle, except in narrow circumstances and provided appropriate safeguards are in place;
 - New GDPR legislation acknowledges the need to balance research and innovation against privacy and data protection;
 - If there is genuine scientific research at stake, this will occupy a new privilege position;
 - Researchers can even go beyond the purposes for which they first collected the data provided there is a legal basis and that appropriate safeguards are in place.

Summary (cont.)

3. Role for ethical requirements from non-legal parameters

- Ethics had been outside the relevant debate on how to protect rights and other interests of the individual. The GDPR regulation is part of the answer. There is an urgent need to establish ethical parameters.
- In October, European Data Protection Supervisor will host the 2018 International Conference of Data Protection and Privacy Commissioners to focus on Digital Ethics.
- “The 2018 International Conference will address this challenge by asking whether an ethical approach is needed to regulate the digital world and, if so, how this approach might be developed and implemented. This is a pivotal moment and we must act to ensure that technology is designed and developed to serve humankind and not the other way around.”
- In conclusion, integrating ethical and privacy requirements in the design of technologies is and will be a milestone for this conference.

Thanks!