CORE-MD Webinar #10

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European Regulatory Framework

- Introduced in 2017
- Aim to increase safety and quality of medical devices
- Several thousand medical devices in daily use will need new approval
- Do the benefits of the new MDR regulation outweigh the possible negative impacts

Impact on patients

- May cause delay in patient access to devices
- Evaluation of older devices could retard introduction of new devices
- The MDR will markedly increase costs associated with:
  - Increased clinical evaluation
  - Access to data
  - Post Marketing Surveillance

Impact on Medical Device Industry

- Need to reevaluate and re-certify existing devices
- Need to conduct additional clinical testing and data collection
- MDR may lead to a reduction in innovation as companies focus on re-certification
- MDR changes may push work in the direction of the FDA

Questions

- When submitting to the FDA –
  - QSub process – obtaining feedback prior to an intended premarket submission
  - Time frame for obtaining market approval significantly shorter
  - Allows access to a much larger market (43% of the global market share)
- When submitting to the EU
  - The European Association for Medical Devices of Notified Bodies estimate a capacity of 6300 certificates a year but 14 000 set to expire in 2024
  - Many Notified Bodies not taking new clients(extension of transition period)
  - Notified Bodies and Approved Bodies are forbidden from having a meeting with manufacturers pre-submission
  - Innovative Devices Access PAthway

Conclusion

- Uncertainty and changes in regulation present new challenges
- Limited Approved Body and Notified Body Capacity
- Structure of MHRA
  - Separation of Devices and Medicines
  - Greater transparency

- Need to look at utilization of
  - Off label data
  - Real World data

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For good.

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