



Medicines & Healthcare products
Regulatory Agency

Security: Needs and Challenges - Regulator's Perspective

IMDRF 2022

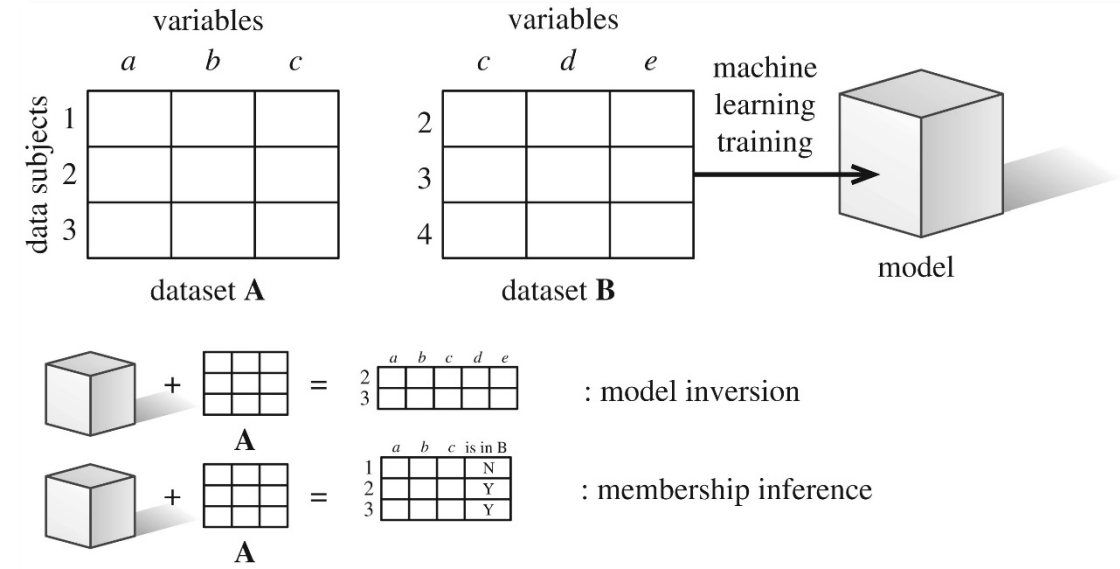
Johan Ordish

12 September

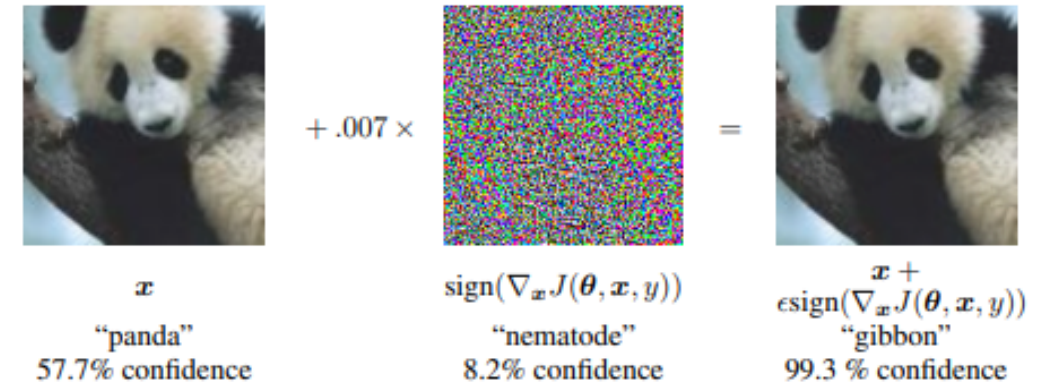


Themes on security for SaMD/ SiMD

1. The relationship between safety and security
2. The relationship between ‘injury’ and loss of personal data and breach of confidentiality
3. Shared nature of the responsibilities
4. Scale
 - 223 NHS Trusts across the NHS Estate
 - ~ > 3,000 “connected medical devices” within each Trust alone
5. Legacy devices
6. Sometimes insecure estates
7. Increasing quantity of direct to consumer SaMD
8. Complexity in ensuring vulnerabilities are reported
9. Further challenges that AI can pose



Veale et al (2018)



Goodfellow et al (2015)

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