

# DI@DEM

## Integrated Security Plan for Medical Device Software: Scalability & the Lifecycle



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 691556.



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## DI@DEM - current stage

- fully designed and built system – phase 1
- medical device classification completed
- system validation: ongoing, due in AUG 2018
- service evaluation / regulated study: SEP 2018
- supported by Horizon2020, Health Innovation Hub Ireland
- built by Granite Digital based on reqs capture & SoW



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## DI@DEM's Integrated Plan - 5 areas

- design risk out
- proportionality in risk mitigation
- secure & managed system operation
- user self-regulation
- indemnity



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## Design risk out rests on

- health IT design best practice: input validation, forced event sequencing, patient & practitioner intuitive design
- Regulatory review & requirements definition: know your regulations, know them well!



## Proportionality in risk mitigation

- Know your patients, understand your data and risks
- Risk management plan based on identified risks
- Prioritise your operational measures: e.g. for a 3-mth service evaluation, secure configuration is high priority



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## Secure, managed system operation

- Security configuration for data in flight, at rest
- Secure hosting: data centre certifications & jurisdiction
- Incident Response Plan: agreed R&Rs with Provider
- Business Continuity; Periodic Reviews



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## User self-regulation

- register your users: patients and practitioners
- train them use the system securely incl. updates
- password policy; 2-f authentication
- Helpdesk service



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## Indemnity

- Professional indemnity – healthcare professionals
- Institutional indemnity – trial sites e.g. hospitals, unis
- Patient insurance (if required for higher risk products)
- Corporate: enterprises trialling health products





## Essential Requirements & Standards Compliance

- consistent, electronically held documentation to demonstrate conformity and compliance
- ISO 62304; 14971; 13485 for CE accreditation



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## Conclusions

- Scalability enabled with security as cross-cutting theme: getting the basics right enables scalability.
- Lifecycle: Security Plan is the custodian of the system, from design to regulatory review, to operation, and decommissioning.



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## Thank You

## Your Questions

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