GOVERNANCE DESIRE©: DESIGN, SPECIFY, IMPLEMENT, ASSURE
DESIRE - DEsign, Specify, Implement, assuRE

• What we can do now…

DESIGN

founded on First Principles: distil requirements, develop solution

SPECIFY

the rules, guidance and expectations

IMPLEMENT

use the right tools for the specifications

ASSURE

Quality Seal for Research Platforms QS4RP
First Principles - 😊 DESIRE not ire 😞

• Don’t WannaCry 😊
• Demonstrate trustworthiness 😇
• Develop relationships with 😗

the “Natural Person”
honouring how people want their data used

the Data Source
their legal and ethical responsibilities will not be compromised

the Data Processor
security expectations have to be tractable
Core Principles: Transparent Trustworthiness

- Development of solutions are open to all interested parties
- Design of solution is open to comment
- Implementation is negotiable
First Principles - Realistic Design and Specification

- If specifications are unrealistic or cannot be implemented with existing solutions or latest advances, they cannot be specifications.
- No reinvention - if someone has developed one earlier…
- No solutions looking for problems - understand the need and match against latest advances.
  - Blockchain, Differential Privacy, Homomorphic Encryption…
Design

- Regulatory and good practice requirements (enshrined in QS4RP Process)
- Codes of practice
- Standard operating rules and procedures
- Baseline security guidelines:
  - minimum security tools that need to be in place
  - firewalls
  - physical protection
  - intrusion detection
  - frequent core infrastructure and tooling software updates
  - openly audited - in terms of management and activity
Specify

- Access control rules, roles and privileges, purposes etc.
- Audit rules and audit log access
- Security policies covering networks of patient data sources
- Determine what can be implemented immediately and what lends itself to newer tools and approaches
Implement

- JFDI!
  - where this is practicable
- Capitalise on existing efforts for deploying newer tools
- Manage expectations - don’t get an ant to push an unnecessary juggernaut
- Iterative
- Blockchain - being used for Audit and transparency (DeepMind)
  - can it be used for managing consent and contractual elements that the consent asserts?
assuRE: Quality Seal for Research Platforms

• Assures all stakeholders of the reliability and trustworthiness of the platform and services
• Assesses and then recognises the competence of the service provider
  • in upholding privacy protection legislation and information security standards
  • in complying with the i~HD Principles and Standard Operating Rules
• Accelerates adoption of harmonised approach throughout Europe
  • gives confidence to all parties that products, processes and services fulfil specified requirements/criteria
Stage 1: Statement of Interest and Application

Step 1: Potential Applicant requests information about QS4RP

Step 2: i-HD Replies to Potential Applicant

Step 3: Applicant submits application

Step 4: i-HD sends agreement package, applicant returns signed agreements

Stage 1 Procedures Owner: i-HD

Stage 2: Assessment

Step 5: Assessors send Pre-assessment Questionnaire, Applicant completes and returns it; Assessors provide Applicant initial report

Step 6: Initial onsite review (1-2 days) Assessors visit Applicant to identify issues; Assessors provide report advising Applicant of work needed to achieve quality labelling

Step 7: Assessors carry out final onsite assessment (2-3 days), evaluate results against quality criteria and write up report for QS4RP Panel and Applicant

Stage 2 Procedures Owner: EUROREC

Stage 3: Award Determination

Step 8: i-HD evaluates report to determine award of Seal

Step 9: i-HD awards seal - OR - requests re-assessment (return to Stage 2)

Step 10: Applicant and i-HD stay connected

Stage 3 Procedures Owner: i-HD
So what do we **DESERVE**?

- We need the patient community to help us answer that…