GenoMed4All & ERN-EuroBloodNet

Educational Program on AI in Hematology for an expert audience

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Regulatory Framework

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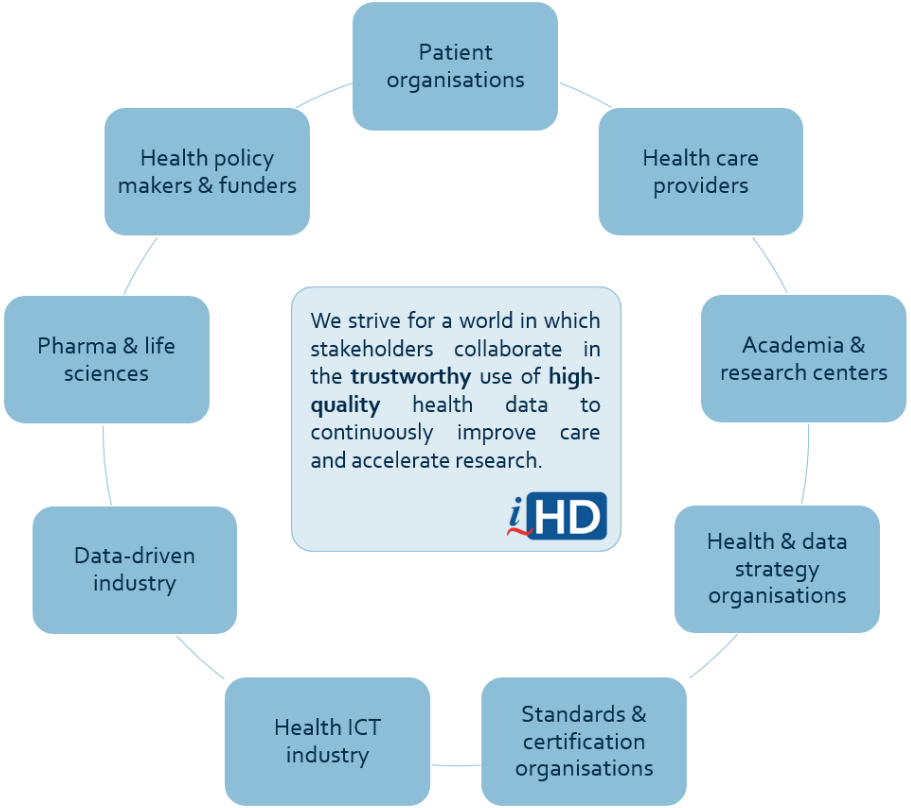
Today's Webinar

Subtitle here

- Introduction
- Setting the Scene
- The GenoMed4All Journey
- The Changing Landscape: the AI Act
- What to Take Away
- Q&A

The European Institute for Innovation through Health Data

- Not-for-profit membership organisation
- Multi-stakeholder, Neutral
- European & beyond
- Registered in Belgium, based in Ghent
- Facilitating optimal uses of health data through series of complementary services focussed on regulatory understanding, data quality, policy and engagement activities



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Nathan Lea

Subtitle here

- Information Governance Lead and DPO, The European Institute for Innovation for Health Data (i~HD)
- Trusted Research Environment Lead, Cancer Research UK
- Patient Representative, UCLH NHS Foundation Trust BRC Data Trust Committee
- Independent Digital Health Innovation Consultant

Setting the Scene

It’s a journey

Evolving Regulatory Framework

Subtitle here

- General Data Protection Regulation (GDPR)
- Data Governance Act
- Artificial Intelligence Regulation
- European Health Data Space
- Individual National Laws (Member States and Third Countries)
  - Medical Professional Confidentiality
  - Research Governance
  - Human Rights
  - Common Law and Statutory Provisions
  - Provisions for Genetic Materials

Tapestry of Governance

GenoMed4All's Challenges

- Multi-centre, multi-national
  - Different processes and procedures
  - Different expectations and outcomes for oversight
  - Different languages
- "Sensitive" data from rare disease cohorts
  - Genetic data, images
  - SCD, MM, MDS
- Cutting edge technology
  - Omics processing, AI
  - High data processing needs
- Shifting regulatory landscape
- Novel technology anxieties: need to develop understanding across stakeholders including citizens to regulators to triallists to clinical teams to developers...

Regulatory Compliance

GDPR

- Concerned with data processing (Transparency, Accountability, Security, Lawful Purpose and Bases)
- Focus on protecting Rights and Freedoms
- High Risk Processing must be assessed
- GDPR mandates a Data Protection Impact Assessment (DPIA)
- Responsibility of Data Controllers

Ethics

- Ethics focuses on participant risk of harm & safety, equity, autonomy and rights
- Emphasises role of consent
- Requires Independent Review Board (IRB) approval
- Research is only lawful with IRB approval

GenoMed4All's Challenges

Ethics and Data Protection in Harmony

- One cannot exist without the other
- Without IRB approval research as a Purpose under GDPR is not **lawful**
  - (with few exemptions)
- IRB assesses ethics and risk of harm
- Data Controller assesses Data Protection Compliance Risk
- Both must work in harmony
- How do we meet this challenge in a large consortium with partners over all EU (and beyond)?
  - Different interpretations of GDPR
  - Source partners are at different stages and requirements for IRB reviews
- Need to balance out Data Management Plan, Open Data and FAIRness
- Need to keep abreast of the EU AI Regulation Drafts.

“Dynamic Tapestry”

Evolving Regulatory Environment and centrality of the AI Act

PRACTICAL: GDPR – especially rights relating to automated processing

- “Closed Loop” only
- Less useful after the fact in many health related cases
- Data Governance Act – altruism and trusted intermediaries

PRACTICAL: Clinical Trials Regulation, Medical Device Regulation, EHDS

- EMA / CE marking
- Health Technology Assessments
- Data Quality and Integrity
- FAIR data

ETHICAL: National and international Policy and Principles documents

- About 75 principles…?
- Probably 30 distinct ones
- Europe, China, US
- Assessment List for Trustworthy AI

BOTH: Traditional medical and scientific research regulatory frameworks

- Independent Ethics Review
- Integrity of Research Conduct
- Standards around Results and their reliability

GenoMed's Journey

GenoMed4All's Approach

Data Protection by Design and Default

- GDPR recommendation
- Helped to map out who our partners are and what they planned to do *specifically*
- Helped us understand nature of the data and what processing
- Highlighted wider regulatory compliance needs
  - Research Governance – including local Independent Review Boards application support
  - Protocol., Information Resources and Informed Consent Forms
  - Wider party onboarding
- Tooling used
  - Data Management Plan – European Commission Template Based
  - Data Protection Impact Assessment – for the Project overall to inform partners to achieve their own compliance
- Emphasis on consistency in understanding of participant involvement and required data flows

GenoMed4All's Approach

Managing the Baseline Compliance

- Approach allowed collegiate working
- Roles could be assigned
  - Joint Controllership
  - Processors and Sub-Processors
- Data Controller responsibilities could be met
  - Consistent DPIAs
- Sponsor responsibilities could be met
  - Template ICF and PILs
  - Could be translated
- These formed the basis of other requirements
  - Data Sharing Agreements
    - One Joint Controller Agreement for each Use Case
    - Based on a European Commission Template
  - Codes of Conduct

Working as a Team

Filling in the gaps...

- EAB – helped us look at the overall ethical implications and latest tools
- Suggested the use of the ALTAI framework to address growing AI compliance needs
- Provided a multi-stakeholder view of the challenges
- Helped us to address the first review of GenoMed4All for newer regulatory compliance
- This ended up aligning well to the AI Act Compliance Requirements...

The Changing Landscape

The AI Act

Assessment List for Trustworthy AI

- From European Commission established Independent High Level Expert Group on AI: ETHICS GUIDELINES FOR TRUSTWORTHY AI and the ASSESSMENT LIST (ALTAI)
- This underpins the AI Act

See https://www.aepd.es/sites/default/files/2019-12/ai-ethics-guidelines.pdf

AI Act Itself...

- Enacted August 2024
- To be taken Alongside GDPR, DGA, DA, MDR, EHDS…
- Impacts in context – especially for “High Risk” Systems
- Independent review by a notification authority, competent authority oversight

High Risk Systems...

Biometrics and identification

Critical infrastructures (e.g transport), that could put the life and health of citizens at risk;

Educational or vocational training, that may determine the access to education and professiona course of someone's life (e.g. scoring of exams);

Safety components of products (e.g. medical devices, AI application in robot-assisted surgery);

Employment, workers management and access to self-employment (e.g. CV-sorting software for recruitment procedures);

Essential private and public services (e.g. emergency services, credit scoring denying citizens opportunity to obtain a loan and access to services);

Law enforcement that may interfere with people's fundamental rights (e.g. evaluation of the reliability of evidence);

Migration, asylum and border control management (e.g. verification of authenticity of travel documents);

Administration of justice and democratic processes (e.g. applying the law to a concrete set of facts).

AI Act Roles

AI User	AI Provider	AI Deployer	AI Importer
AI Distributor	Authorised Representative	AI Operator	Affected Person

Governance and Notification:

Conformity Assessments, Certifications, Declarations and Notifications

Each Member State will identify its own Notification Body

High Risk systems will apply to the bodies for certifications

They will provide evidence of assessments and declarations

This relies on Quality Management Systems and internal assessments

An AI Board will be established to oversee implementation of the regulation

Competent Authorities will oversee this at Member State Level

Post Market Surveillance, Codes of Conduct and “Crime and Punishment”

Performance and serious incident reporting

Documentation will need to be made available

Codes of Conduct to encourage voluntary submission for non High Risk Systems

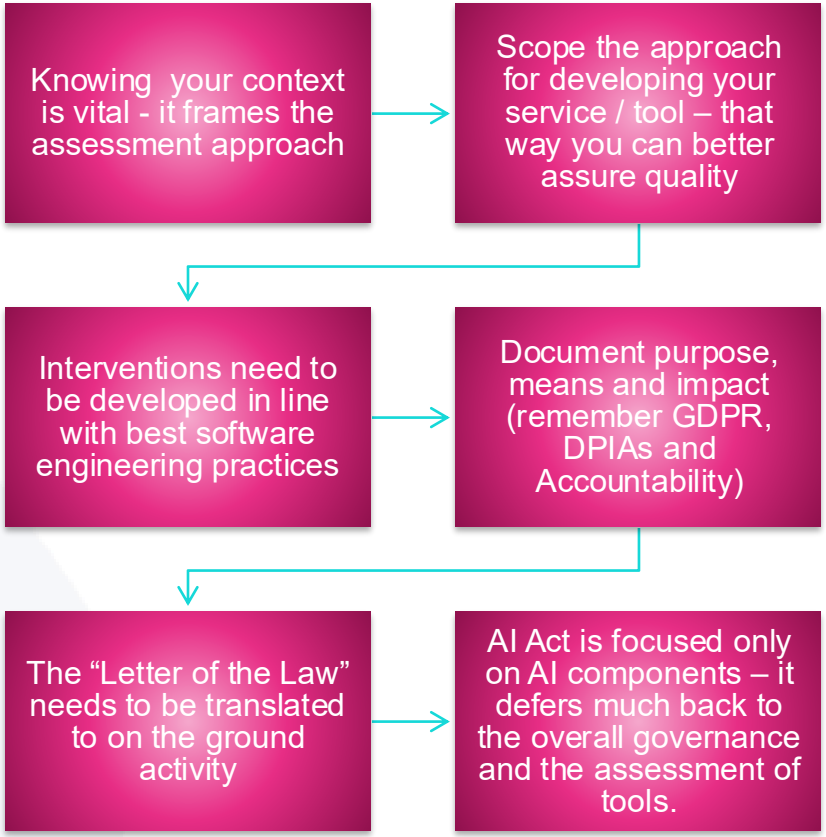
Infringements of the Act will be assessed and prosecuted by Member States (likely GDPR Supervisory Authorities)

Up to €30M or 6% of Annual Global Turnover (with variations)

European Data Protection Supervisor will police EU institutions

What to Take Away

Key Focuses


Knowing your context is vital - it frames the assessment approach
Scope the approach for developing your service / tool – that way you can better assure quality
Interventions need to be developed in line with best software engineering practices
Document purpose, means and impact (remember GDPR, DPIAs and Accountability)
The “Letter of the Law” needs to be translated to on the ground activity
AI Act is focused only on AI components – it defers much back to the overall governance and the assessment of tools.

Why this is Important

Case in Point – UK Post Office and Horizon system scandal

Clear issues with understanding and assessing quality of a new system

Where was independent quality assessment and implementation oversight?

Judiciary along with investigators took Horizon system information as accurate when it was not

Why this is Important

Case in Point – UK Blood Transfusions Scandal

Thousands of people affected from contaminated samples from US containing HIV and Hep C.

Donations came for payment from a high risk group where these viruses were not routinely scanned for.

Report due – but this is what happens when high risk interventions do not reach a standard.

Thank You!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Questions and Comments!

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This is a highlight!

Thanks!

Any questions?

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