MY HEALTH
MY DATA

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eHealth Week 2017 – Malta - May 11th

eHealthWeek 2017 – two key sentences from the yesterday's plenary session

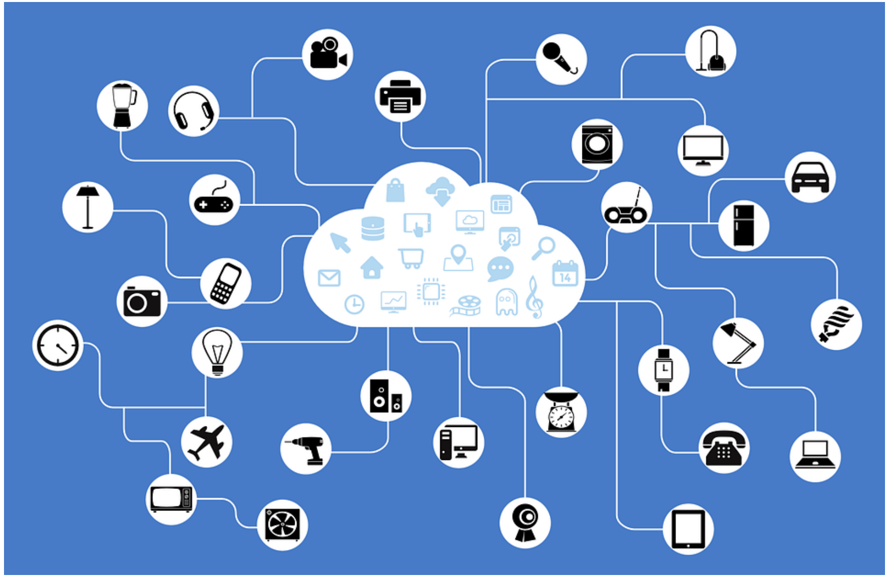
- **EC Commissioner Vytenis Andriukaitis** has stressed the importance of "**patient empowerment** and **patient-centred care**"
- **HIMSS's CEO Stephen Lieber** talked about "Heath data **usage and sharing issues**"

The big data revolution in healthcare

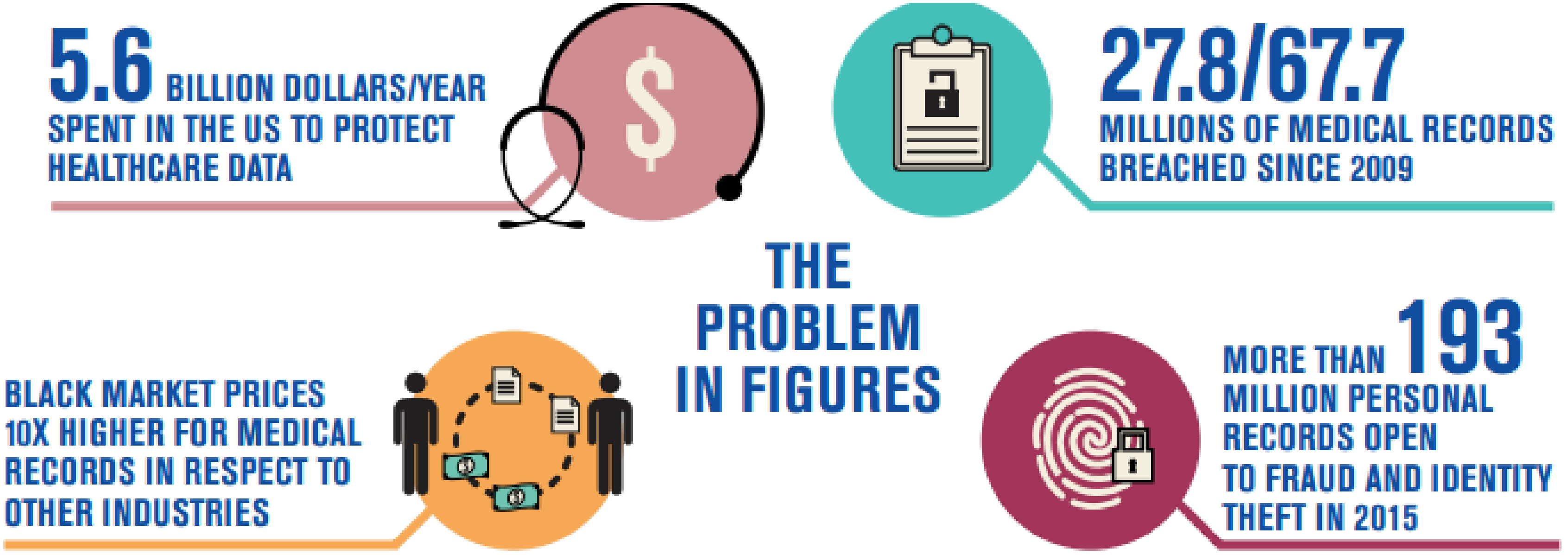
- With **its 150 exabytes of stored data worldwide per year**, Healthcare is a bright example of **“data explosion”** phenomenon

mHealth mIoT

- Within 2020 – **40% of IoT technologies will be healthcare-related**
- This will be the basis of hte “Internet of Medical Thing” (IoMT), o **medical Internet of Thing (mIoT)**



Key figures



THE PROBLEM IN FIGURES

5.6 BILLION DOLLARS/YEAR SPENT IN THE US TO PROTECT HEALTHCARE DATA

27.8/67.7 MILLIONS OF MEDICAL RECORDS BREACHED SINCE 2009

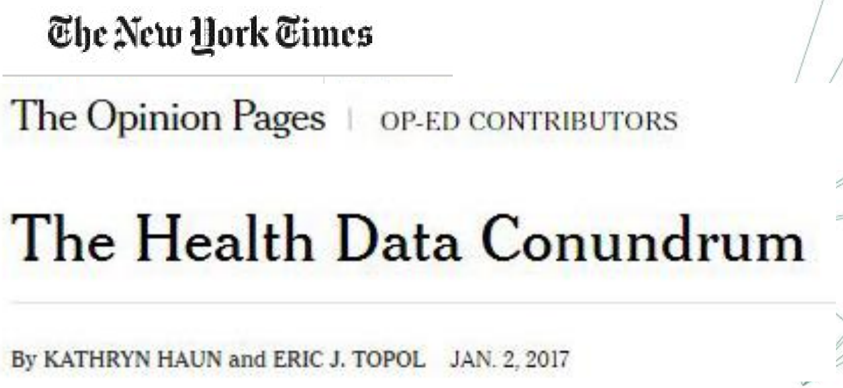
BLACK MARKET PRICES 10X HIGHER FOR MEDICAL RECORDS IN RESPECT TO OTHER INDUSTRIES

MORE THAN **193** MILLION PERSONAL RECORDS OPEN TO FRAUD AND IDENTITY THEFT IN 2015

A new civil right to personal health data ownership

“[We shall overcome] the old, paternalistic model in medicine in which the data is generated and owned by doctors and hospitals”…

“Patients should be the owners of their own medical data. It’s an entitlement and civil right that should be recognized”.



The New York Times

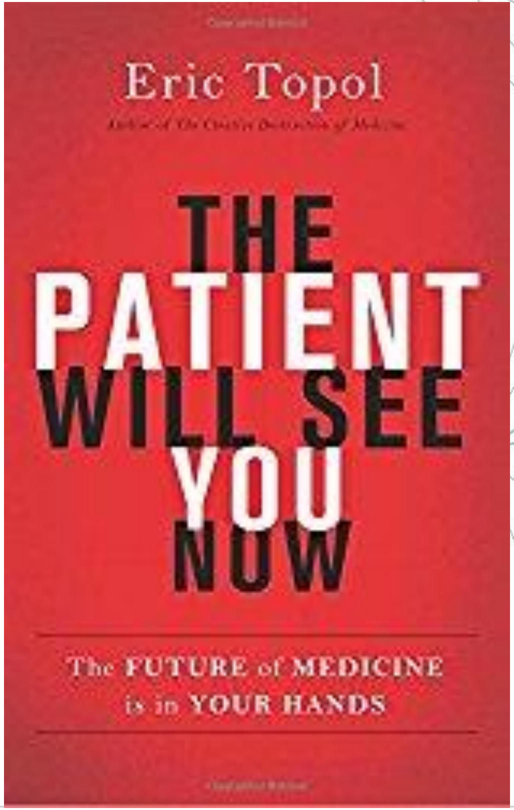
The Opinion Pages | OP-ED CONTRIBUTORS

The Health Data Conundrum

By KATHRYN HAUN and ERIC J. TOPOL JAN. 2, 2017

The patient at the centre

- This will also apply to patient, who is *“**the single most unused person in health care**”***.**
-
- Thanks to mIoT, smartphone, and Personal Data Account, a new era of **healthcare democratisation will start**.



Eric Topol

Author of The Creative Destruction of Medicine

THE PATIENT WILL SEE YOU NOW

The FUTURE of MEDICINE is in YOUR HANDS

The General Data Protection Regulation

- ***Data access*:** “A data subject should have the right of access to personal data which have been collected concerning him or her”

- ***Right* to *data portability*:** receive personal data in a **structured, commonly used, machine-readable and interoperable format**”

The GDPR and the Patients' consent

- **Freely given**, **informed**, and **specific**
- **Easily readable**, and in **plain language**
- Data Controller will have to **demonstrate consent**

MHMD goals

- **CITIZENS’ EMPOWERMENT**

  (PDA, dynamic consent, smart contracts)

- **DATA PRIVACY AND SECURITY**

  (blockchain, de-identification, encryption)

- **DATA VALUE ENHANCEMENT**

  (blockchain, big data analytics for pseudo/anonymised data)

MyHealthMyData – Basic Facts

- Grant agreement no: 732907 - EC Budget 3.455.190,00
- Duration: 1st November 2016 – 31 October 2019
- Consortium:
  - **5 SMEs:**

Lynkeus (Italy) [Coordinator], Digi.Me (UK), HW Communications (UK), Gnúbila (France), SBA Research (Austria)

- **4 Clinical partners:**

Ospedale Pediatrico Bambino Gesù (Italy), Deutsches Herzzentrum Berlin (Germany), Queen Mary University London (UK), University College London (UK)

- **4 Research centres and Academia:**

Athena Research (Greece), Consiglio Nazionale delle Ricerche (Italy), HES-SO (Switzerland), Universitatea Transilvania din Brasov (Romania)

- **1 Legal consultancy:**

Panetta&Associati (Italy)

- **1 Industry:**

SIEMENS Healthcare (Germany)

MHMD Peculiarities and Mission

- **Biomedical**

  Issues of data subjects' privacy and data security represent a crucial challenge in the biomedical sector, more than in other industries

- **Privacy and Security**

  This makes it the ideal field to build and test new models of privacy and data protection, and the technologies that encode them

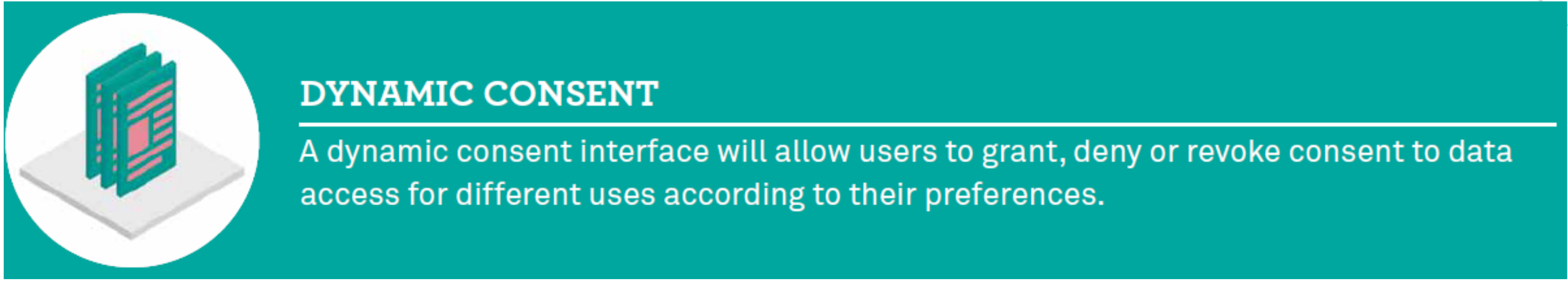
- **Blockchain and Personal Data Accounts**

  MHMD aims at changing the existing scenario by introducing a distributed, peer-to-peer architecture, based on Blockchain and Personal Data Accounts.

- **New mechanisms of trust and value-based relationships**

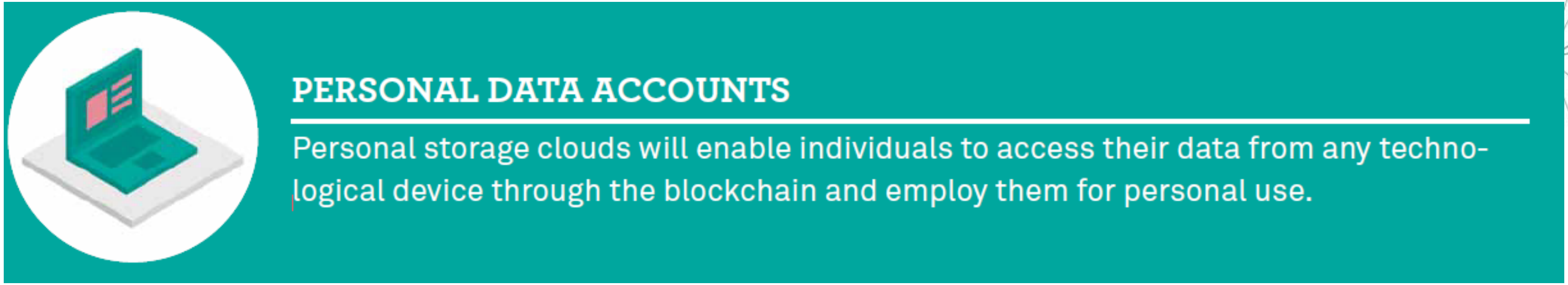
  MHMD is developing new mechanisms of trust and of direct, value-based relationships between people, hospitals, research centres and businesses, in what is going to be the first open biomedical information network centred on the connection between organisations and the individual.

MHMD key innovations (1)



DYNAMIC CONSENT

A dynamic consent interface will allow users to grant, deny or revoke consent to data access for different uses according to their preferences.



PERSONAL DATA ACCOUNTS

Personal storage clouds will enable individuals to access their data from any technological device through the blockchain and employ them for personal use.

Dynamic Consent

- **Dynamic Consent allows to extend traditional consents, combining them into a user workflow in which patients may or may not allow access to their data based on a range of key parameters:**
  - What will data be used for
  - What will be done with the data
  - What data will be retained
  - What data will be shared with 3rd parties and for what purpose
  - How will the right to be forgotten be implemented
  - Define post-mortem usage or donation of personal data.

Key MHMD User Entitlements

- **Aggregate personal data from disparate sources:**

  Social media accounts, clinical data repositories, personal drives, wearable devices, etc., in a single, user-owned account (PDA).

- **Assign data access rights on the basic of user-defined consent**

- **Stay informed of, and enquiry on, relevant data transactions after access has been granted**

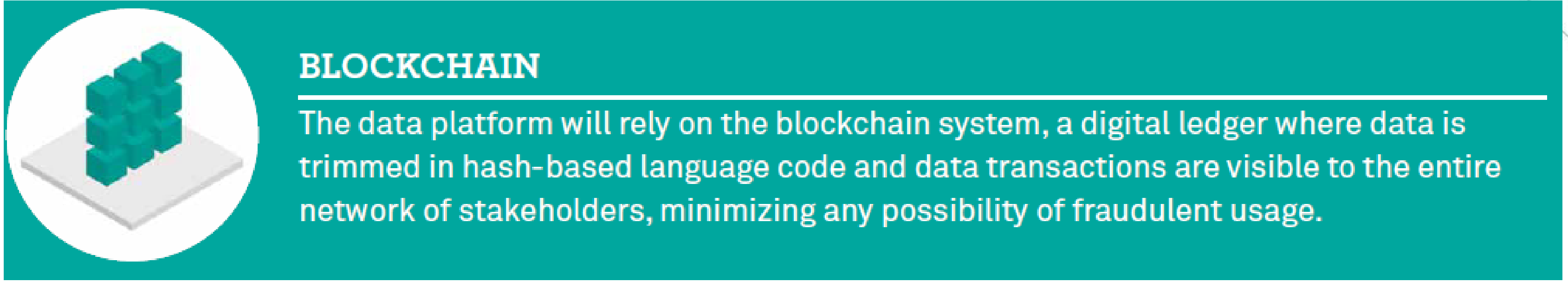
- **Be able to revoke data access rights, or extend them**

- **Be able to receive requests from stakeholders for data access permissions**.

  Requests may also include incentives offered by stakeholders in exchange for data

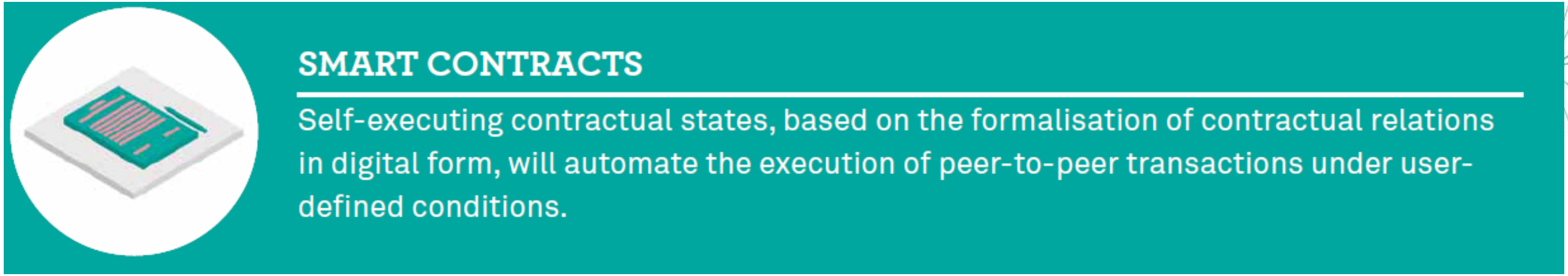
- **Define post-mortem usage or donation of personal data**

MHMD key innovations (2)



BLOCKCHAIN

The data platform will rely on the blockchain system, a digital ledger where data is trimmed in hash-based language code and data transactions are visible to the entire network of stakeholders, minimizing any possibility of fraudulent usage.



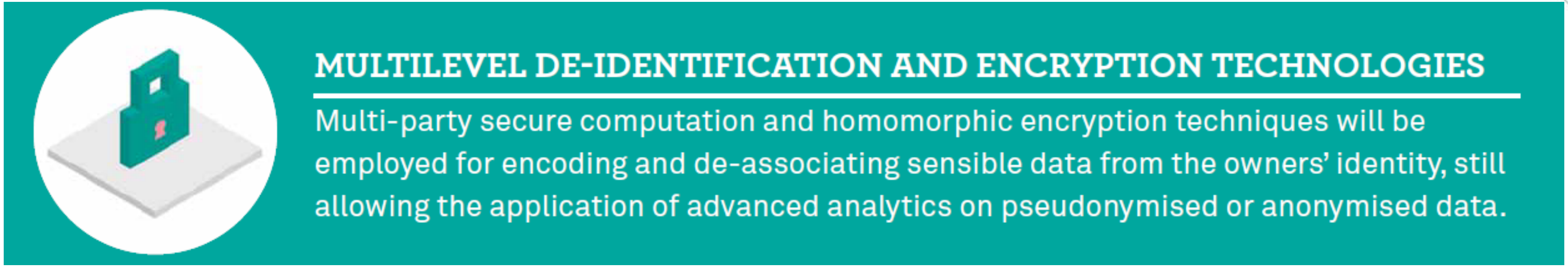
SMART CONTRACTS

Self-executing contractual states, based on the formalisation of contractual relations in digital form, will automate the execution of peer-to-peer transactions under user-defined conditions.

Blockchain: no recourse to Trusted Third Party

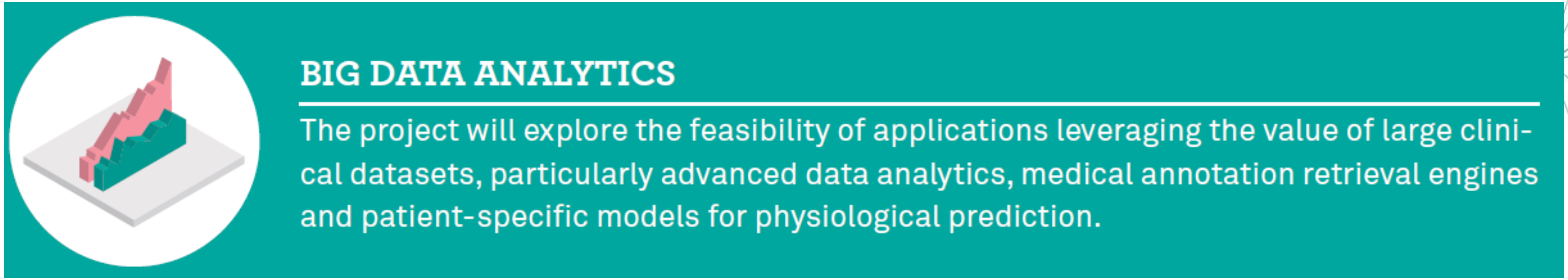
- **Applying the blockchain approach to health data guarantees secure access from anywhere on any device**
- **The Blockchain ledger is the secure, non-editable record where:**
  - All transactions are confirmed by the network as entries forming blocks of transactions
  - The whole network monitors the legitimacy of each transaction, guaranteeing a distributed control system
- **Each stakeholder can enact anonymous transactions through the ledger:**
  - Employing public key encryption for identifying owners in the ledger, recording one half of the public key pair
  - Only the person or istitution holding the corresponding private key can decide what happens next to their data
- **Each stakeholder is equipped with a ‘wallet’ containing:**
  - An encrypted identifier
  - His/her Dynamic Consent
  - His/her data access policy file

MHMD key innovations (3)



MULTILEVEL DE-IDENTIFICATION AND ENCRYPTION TECHNOLOGIES

Multi-party secure computation and homomorphic encryption techniques will be employed for encoding and de-associating sensible data from the owners' identity, still allowing the application of advanced analytics on pseudonymised or anonymised data.



BIG DATA ANALYTICS

The project will explore the feasibility of applications leveraging the value of large clinical datasets, particularly advanced data analytics, medical annotation retrieval engines and patient-specific models for physiological prediction.

A long story of EU-funded research

Health-e-Child

From FP6…

Sim-e-Child

MD-PAEDIGREE

CARDIOPROOF

Passing through FP7…

To H2020

MY HEALTH
MY DATA

MHMD and the strategic role of the Four Leading Hospitals

- Following the example of routine data inflow by the OPBG PCDR, and the interoperability system established in Cardioproof and MD-Paedigree

- Taking into account the less restricted data processing allowed by the GDPR when it is aimed at scientific research, and the proviso that the data protection legislation does not apply to anonymous/duly anonymised data

- Guaranteeing that all health and personal data will:
  - Be duly anonymised before been uploaded on MHMD Infostructire
  - Be processed, should the use of partial anonymisation techniques be indicated for the intended use of data, on the ground of a Dynamic Consent provided by the data subjects.

- Exploring different open data implementation approaches

- Evaluating, to the extent permitted by national and European regulation, solutions providing some concrete acknowledgment of data value

OPBG’s role in MHMD

- OPBG represents the largest clinical center involved in the study.
- OPBG will oversee the implementation of the tools for individuals’ rights implementation for personal data ownership and control.
- OPBG will make sure that the developed tools are in line with the standards ethical requirements and relevant regulations
- OPBG will also test and validate the final platform, assessing its usability in data management, exchange, research activities and patient relationship.

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