

# Implications of the Innovative Medicines Initiative (IMI) for patients

*How to better communicate information on medicines for children*

## Towards digital health

Delivering safe information on medicinal products in Europe  
European Economic and Social Committee

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**Francis P. Crawley**

Clinical Practice Alliance – Europe

[fpc@gcpalliance.org](mailto:fpc@gcpalliance.org)



# The Vantage Point

- EU GCP Dir/Reg and Paediatric Regulation
- Chair WG, *Guidelines and Recommendations for European Ethics Committees* (Brussels 1995/7)
- Past member **UNAIDS** ERC
- Chair **WHO** WGs on Guidelines for Ethics Committees & DSMBs
- Co-founder, Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
- Past Member, WHO GCP & ICTRP Committees
- Member, EORTC IRB; Chair, INCTR EC
- Member, EWG, **European Academy of Paediatrics**
- Co-founder, European Network for Research on Alternating Hemiplegia (**ENRAH**)
- EUROSOCAP, **ENCCA**, **nEUroped**, **RESPECT**, EBC



# Three Key Points

- The objective: a **European Health Library (EHL)**
- The tool: **custodianship**
- Where to begin: **children's health**

# IMI for Patients, for Children

‘Big Data for Better Outcomes’

*Concept for an IMI2 programme*

Coordinating and making efficient investments in large health and population datasets for improved health outcomes, personalized products and services, and advanced therapies in a European model of economic efficiency

# The EESC

## The European Digital Agenda

‘A Digital Agenda for Europe’

COM(2010) 245 final

2.3 Given the commitment to eInclusion in the Digital **[Health]** Agenda, the Council should support initiatives across the EU to introduce school children, older citizens, and socially disadvantaged citizens to the use of broadband **[health]** technology (e.g. Web-based learning, video conferencing, on-line public services, etc). All education **[healthcare]** programmes should be based on best practices. 5

# The EESC

## European Digital Health

**‘Towards digital health  
*Electronic information for safe use  
of medicinal products*’ (Draft)**

1.2 The Committee notes that *people seeking information*, patients and healthcare professionals have repeatedly stressed **the need for full, accurate and up-to-date information on medicinal products** and for a single digital market.

**‘a trustworthy and accessible source of officially  
authorised information’**

# Three Key Concepts

- ‘Health is wealth.’
- ‘My health is our health; our health is my health.’
- Health is a shared responsibility.

# The European Health Library

## Data (including 'Big Data')

- Patient data
- Research data
- Treatment data
  - Images
- Biological materials
  - Pictures
  - Video

# The European Health Library

- Nomenclatures
  - Definitions
  - Descriptions
- Diagnostic protocols
- Treatment protocols
- Research protocols
- Research results
- Medical intervention information  
(medicines, devices, imaging, surgery)
- Medical journal articles; Medical textbooks

My story, our story of individual and societal health <sup>9</sup>

# Custodianship

- Health data, healthcare practice, health sciences, health knowledge may *not* be owned
- Health data may not be considered as other kinds of data; health data is a public good
- Replace ‘ownership’ with ‘custodianship’
- Health (data) custodianship = ‘the responsible reception, organization, protection, and sharing of health data, information, and knowledge’  
  
‘the good health custodian’ = ‘the good health librarian’

# The European Health Library

An Open House: Every Citizen is a Doorway

## Health Outcomes

*addressing comprehensive patients' needs*

Good Healthcare Provision  Good Research Practice

Diagnostics  
Prevention  
Therapy

Patient data  
BIG DATA  
Medicines Data

'My Story'  
'Our Story'  
of  
Health

Patients, Healthcare-providers, Sponsors, Researchers  
Ethics Committees, Regulators, Policy-makers

## Custodianship

building a European foundation of trust in health resources,  
health services, health research, and health knowledge

# The EHL

- A public objective
- A public engagement
- A public outcome

the custodianship of European citizens'  
and communities' health

involving all sectors, all members,  
all citizens of the European Community

[fpc@gcpalliance.org](mailto:fpc@gcpalliance.org)