



The Global Connector for Digital Health

European Connected Health Alliance



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Digital Tools supporting Innovative Patient Care: An introduction to Regulatory Aspects

1. Who, Where and What of the ECHAlliance
2. What is healthcare?
3. What are Digital Tools & speed of innovation?
4. Examples of Digital Tools
5. Sector, Legal & EU Regulatory Overview
6. Conclusions



About ECHAlliance

WHO



**Member Organisation
(850+ organisations)**

Companies, policy-makers, research orgs, health & social care providers, patient groups, insurance, procurers, government ministries



**20,000+ experts /
professionals**



**Not for Profit
Organisation**

*Registered in Ireland and
in the UK*

WHERE

**Global reach across
78 Countries and
4.6 billion people**



**International Network of 50+
Digital Health Ecosystems
(80+ ecosystem gatherings a year)**

WHAT



**Connecting
the dots**



**Network of Digital
Health Ecosystems**



**Comms &
networking**



**Supporting
our members**



**Global
Events**



**Funding/
Tenders**



ECHAlliance Ecosystems: basic principles

- **Based on a geographic area**
- Multi-sector stakeholders gathering
- **Accessible to all (no barriers)**
- Permanent, with regular gatherings
- **Light governance via working group**
- Shared strategy & action plan
- **Lead with a need**
- Member of an International network
- **Patients / Citizens at the centre**





Our International Network of Ecosystems – is growing further

- ARGENTINA
- AUSTRALIA – Melbourne
- BELGIUM – Brussels
- BELGIUM – Flanders
- BRASIL
- BULGARIA
- CANADA – Quebec
- CANADA – Ontario
- CHILE
- CZECH REPUBLIC
- CROATIA
- DENMARK – Southern Denmark
- DENMARK – Scandinavia
- Nordic Health 2030
- ENGLAND – Manchester
- ENGLAND – North West Coast
- ENGLAND – London
- ENGLAND – Yorks/Humber
- ENGLAND – South West Coast

- ESTONIA
- FINLAND – Oulu
- FINLAND – Ostrobothnia
- FINLAND – South Ostrobothnia
- FINLAND – Kuopio
- FINLAND – Central Finland
- FINLAND – Helsinki
- FRANCE – Bretagne
- FRANCE – Nice
- FRANCE – Normandy
- GERMANY – Hess
- GERMANY – Nuremberg
- GERMANY – Rheinland
- GREECE – Athens
- HUNGARY
- INDIA
- ISRAEL
- ITALY – Treviso
- LITHUANIA

- MALTA
- MEXICO
- NETHERLANDS – Friesland
- NETHERLANDS – Health Valley
- NORTHERN IRELAND
- NORWAY – Smart Care Cluster
- NORWAY – Health Care Cluster
- POLAND
- PORTUGAL – SHAFÉ Portugal
- PORTUGAL – Digital Health Portugal
- REPUBLIC OF IRELAND
- ROMANIA – Transylvania
- ROMANIA – South West Oltenia
- SERBIA
- SCOTLAND – Highlands & Islands
- SCOTLAND – Scottish Digital Health and Care Ecosystem

- SLOVENIA
- SPAIN – Extremadura
- SPAIN – Valencia
- SPAIN – Galicia
- SPAIN – Catalonia
- SPAIN – Basque Country
- SRI LANKA
- SWEDEN – Västerbotten
- URUGUAY
- USA – New York
- WALES





What is Healthcare

A combination of

- Health Services;
- Social Care Services;
- Well being services;
- Housing; and
- Education

WHO defines health as "a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity."

NB. Wellbeing





Speed of innovation v pace of regulation & sources of compliance?

- Technology develops rapidly. The law does not. In consequence, and with increasing frequency, new technology is being introduced into a legal environment that was not designed to accommodate it.
- Telegraph Act 1869: new technology colliding with old law is not new – telegrams & the newly-invented telephone (Attorney General v Edison Telephone Company 1880).
- Contrast Ethics & Hippocratic Oath e.g. “ **First do no harm** ”
- Soft Law – Codes of Conduct & “ Guidelines ”



How fast do clinical procedures reach patients?

Research into routine practice = **17 years**
Average annual rate of adoption = **3.2 %**

Clinical Procedure	Landmark Trial	Rate of Use study	Rate of Use %	Annual increase in Rate of Use %
Flu Vaccination	1968	1997	55	1.9
Thrombolytic therapy	1971	1989	20	1.1
Pneumococcal vaccination	1977	1997	35.6	1.8
Diabetic eye exam	1981	1997	38.4	2.4
Beta Blockers after MI	1982	1997	61.9	4.1
Mammography	1982	1997	70.4	4.7
Diabetic footcare	1983	1998	20	4.0
Cholesterol screening	1984	1995	65	5.9
Fecal occult blood test	1986	1993	17	2.4

Balas, E. A., & Boren, S. A. (2000). **Yearbook of Medical Informatics: Managing Clinical Knowledge for Health Care Improvement**. Stuttgart, Germany: Schattauer Verlagsgesellschaft mbH.

NUMBER OF YEARS IT TOOK FOR EACH PRODUCT TO REACH 50 MILLION USERS

Automobile



62 years

Telephone



50 years

Electricity



46 years

Credit Card



28 years

Television



22 years

ATM



18 years

Debit Card



12 years



10 years

Internet



7 years

PayPal



5 years

YouTube



4 years

Facebook



3 years

Twitter



2 years



Dictionary Definitions of “ Digital “ Tools

- “Signals or data expressed as a series of digits 0 and 1, typically expressed by values of a physical quantity such as voltage or magnetic polarisation ”
- “ Electronic technology that generates , stores , and processes data”
- **Not much help!**



Some Examples of Digital Tools

- Apps providing information – see <https://orchahealth.com>
- Devices with sensors e.g. wearables (watches or trackers) or car steering wheels for remote monitoring (steps, heart rate, blood sugar)
- Apps “diagnosing” conditions or Dr Google?
- Software which predicts a health event (stroke or heart attack) – predictive analytics
- Software which identifies patterns in health conditions (locations with high disease incidence) - whole population management
- Chat Bots
- Data Sets
- **But let's make it real**

DIGITAL HEALTH ADOPTION

Use of digital health tools by age

**ROCK
HEAL+H**

 **MILLENNIAL**
18-34

40% own a wearable

48% go online to find a physician

34% select a provider based on online reviews

42% have sought medical care or advice over **live video**

 **GEN X**
35-54

26% own a wearable

38% go online to find a physician

21% select a provider based on online reviews

31% have sought medical care or advice over **text message**

 **BABY BOOMER**
55+

10% own a wearable

23% go online to find a physician

8% select a provider based on online reviews

56% have sought medical care or advice over the **phone**

Source: Rock Health 2016 consumer survey data (n = 4,015)

A third of millennials have downloaded a health app in the last 30 days, compared to 20% of Gen Xers and 7% of baby boomers.

CONSUMER = PATIENTS, STUDENTS, STAFF, DONORS...
HUMANS

CARE, LEARNING, WORK, RESEARCH, GIVING...
...LIKE EVERYTHING ELSE DIGITAL



ACCESS

Ease of Access to Jefferson

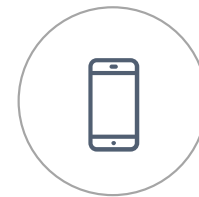
Services



EXPERIENCE

Closed-loop Digital

Experiences



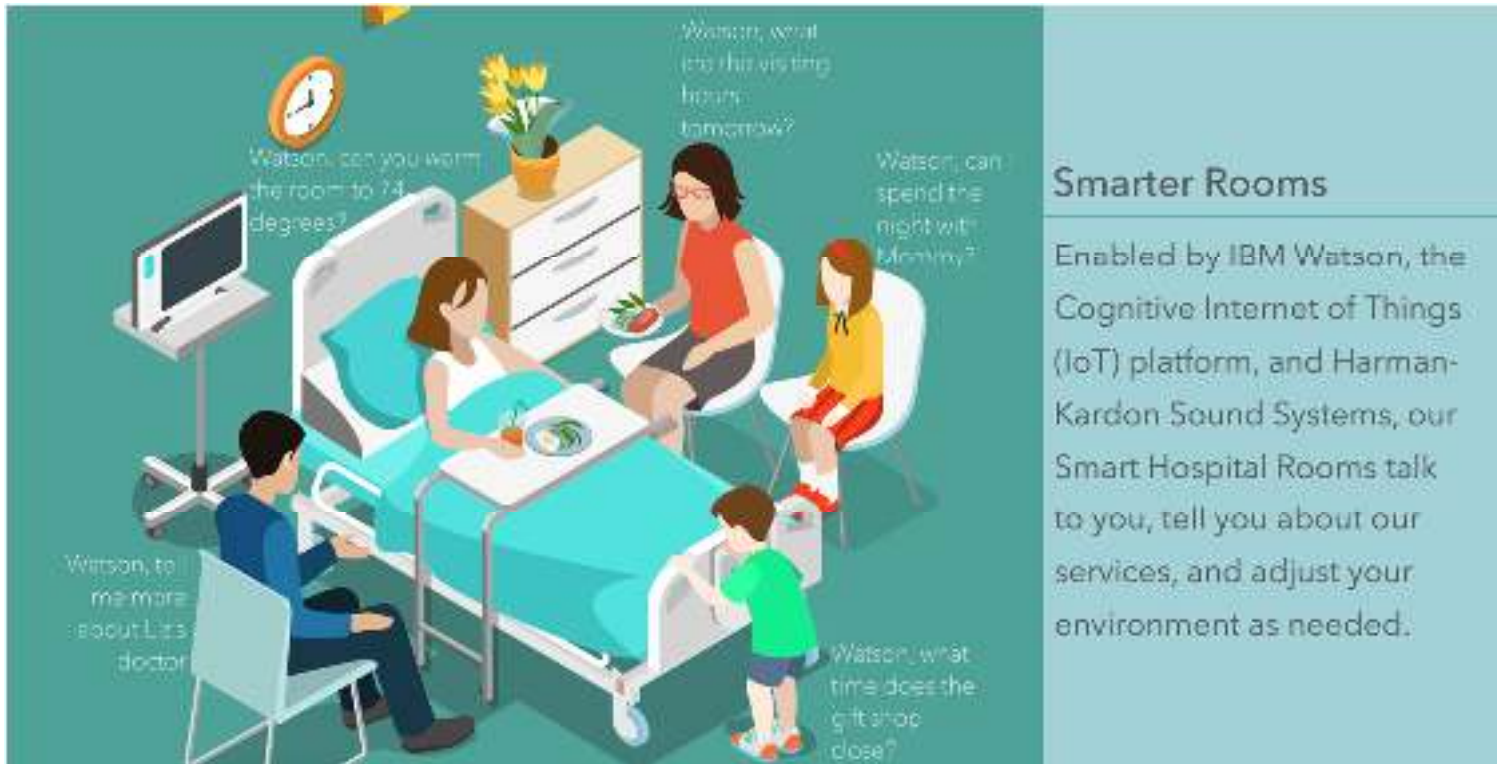
CONVENIENCE

Services via Web, Mobile,

Wearables, IoT, etc.

THE EQUATION FOR DIGITAL TRANSFORMATION @ JEFFERSON

Smart Hospital Rooms & Digital Concierge



TJU HOSPITALS + DICE + COGNITIVE IoT + IBM WATSON + HARMAN KARDON

CONSUMER = PATIENTS

CARE... LIKE EVERYTHING ELSE DIGITAL

If You Can't Get to Your Doctor,
See One of Ours—Online, Anytime, Anywhere



JeffConnect is Here

The Faster, Easier Way to See a Doctor—Virtually!

- Accessible on any phone, tablet, laptop or desktop
- Use in your home, hotel room, car or wherever you are in PA, NJ and DC
- Available 7 days a week, 10:30 a.m. to 8:30 p.m. through September 29, 24 hours a day until September 31.

Download the free JeffConnect app today!  

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JeffConnect

ACCESS | EXPERIENCE | CONVENIENCE

Realtime information Technology Towards activation (RiT-Ta)

- World's first virtual assistant trained in oncology;
- Designed to provide timely, relevant and accessible information any time, place or where to support patients have better conversations as they live with cancer;
- Does she talk, does she walk, does she come complete.....meet RiTTa





GIG
CYMRU
NHS
WALES

Ymddiriedolaeth GIG
Prifysgol Felindre
Velindre University
NHS Trust

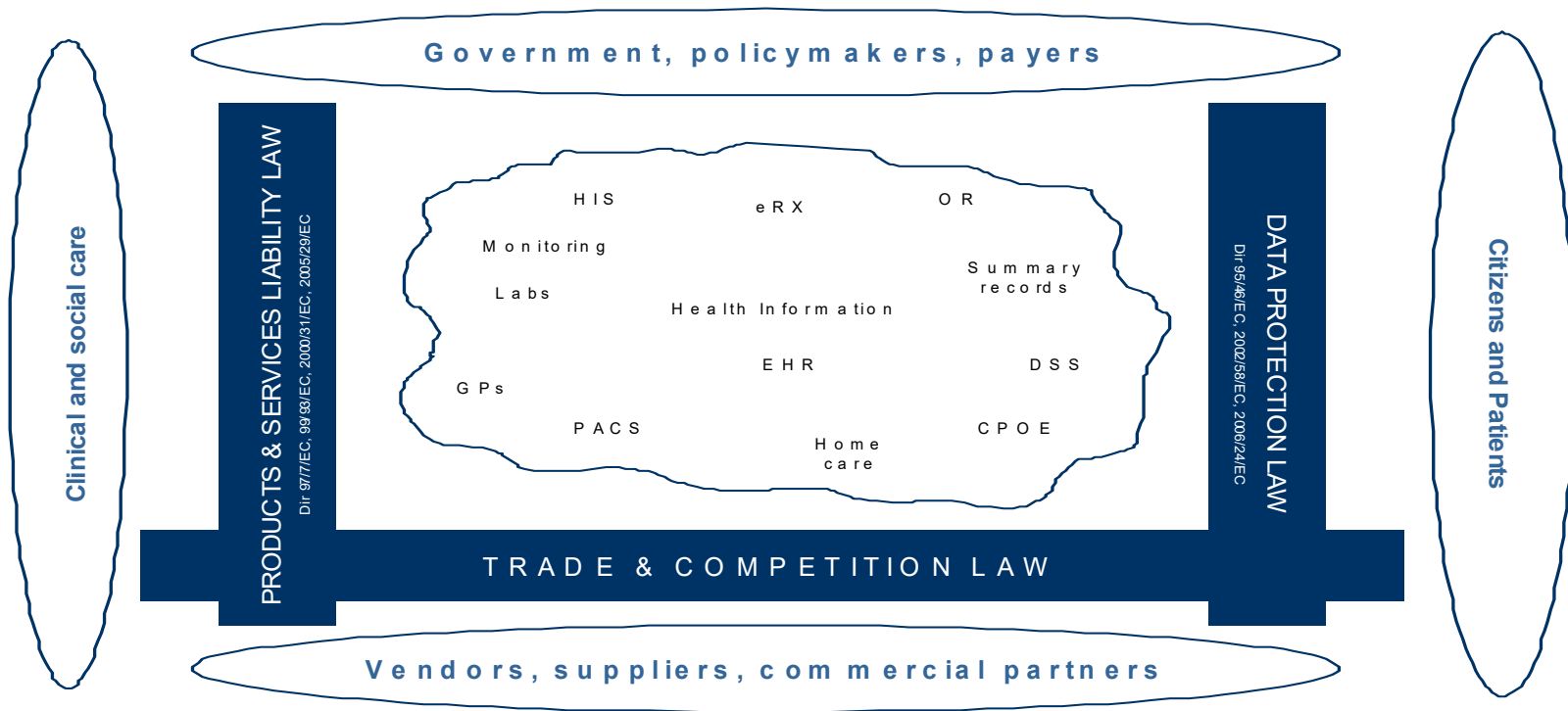


Sector & Legal and Regulatory perspectives

- Pharma, Tech & Medtech are global sectors
- Healthcare services are predominantly regional or national
- Health law is a Member State not EU competency
- But EC has legal powers in related matters e.g. Data Protection , Security, Digital and Consumer laws
- Impact of US litigation
- So regulatory compliance requirements with laws from EU and Member States (which may differ) and from different sectors (not just health e.g. advertising/marketing)
- What is eHealth , mHealth , telehealth, telecare, connected health or digital health?



In 2008 the EC created this Regulatory overview





B2B, B2C and B2B2C?

- MHealth involves the combining of products and services from device manufacturers, telecommunications companies and software producers with some healthcare aspect. This creates three types of services/markets for
- (1) health professionals, (2) health management and (3) prevention and well being.

Health Professionals	Health Management	Prevention & Wellness
Mobile devices for doctors/nurses e.g. scanners	Data Collection	Education & Awareness
Mobile access to Health information and clinical system	Tele assessment	Personal Emergency Alarms
	Remote monitoring	Tracking

Using a device

B2B

B2C



Important EU Regulations

- Data Protection & Privacy: General Data Protection Regulation (GDPR 2016/679)
- Medical Devices Regulation (2017/425)
- In Vitro Diagnostic Devices Regulation (2017/746)
- **Artificial Intelligence Act**
- **Data Act**
- **Data Governance Act**
- **European Health Data Space**

YOUR PHONE TOLD YOUR FITBIT THAT
TOLD YOUR NEST THAT TOLD YOUR
SONOS THAT TOLD ME THAT YOU
OWE YOUR WIFE AN APOLOGY.

TWO DOZEN RED ROSES ARE ONLY
\$29.99 FOR A LIMITED TIME.



TOM
FISH
BURNE



Conclusions

- Is regulation a barrier to innovation? Does an absence of regulation boost growth and productivity?
- Balancing patient safety and innovations in treatments , devices and drugs.
- Difficulties occur in regulatory law not because there is too much of it – on the contrary, there is often too little – but because it is frequently not good enough.
- Businesses want clarity and certainty as to what the regulatory environment looks like.
- A wish for a harmonised healthcare regulatory system across the EU!
- "It is not sufficient that the state of affairs that we seek to promote should be better than the state of affairs that preceded it, it must be sufficiently better to make up for the evils of transition". *J.M. Keynes*



Digital Challenges and Policy Recommendations : Further reading materials

- Digital Health Society Calls to Action <https://echalliance.com/wp-content/uploads/2021/02/210201-CTA-Health-Data-Report.pdf>
- All Policies for a Healthy Europe – Digital Working Group <https://healthyeurope.eu>
- EU Health Coalition – 20 Recommendations <https://healthyeurope.eu>



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Thank you!



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