

Real world evidence in adaptive clinical trial design

Green Paper on mHealth

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**Pēteris Zilgalvis, Head of Unit,
Unit Health and Well Being, DG CONNECT,
European Commission**

1) Green Paper - objective

- The **Green Paper** launched a broad consultation to collect ideas to unlock mHealth potential in Europe
- It is accompanied by a **Staff Working Document** on the legal framework applicable to lifestyle and wellbeing apps
- *Consultation closed on 10 July 2014*

1) Green Paper - Issues identified

1. data protection
2. big data
3. patient safety
4. lack of knowledge about the legal framework
5. mHealth role in healthcare and equal access
6. reimbursement issues
7. interoperability
8. liability
9. research and innovation in the field
10. international cooperation
11. access of web entrepreneurs to the market

1) Green Paper - Issues identified

Big data

*- What are the barriers to fully realise the potential of **mHealth generated data** in the EU?*

Big data potential

- Great opportunities:
 - **help develop new creative products and services, e.g. apps on mobile phones or business intelligence products for companies**
 - **boost growth and jobs in Europe, but also improve the quality of life of Europeans**
- ⑩ Challenges:
 - **Lack of cross-border coordination and legal clarity**
 - **Insufficient infrastructure and funding**
 - **A shortage of data experts and related skills**

4 STEPS TO LEVERAGE THE POTENTIAL OF BIG DATA



1. INVESTING IN IDEAS

Search for **game-shifting** ideas

Public Private Partnership

Research in **Horizon2020**



2. INFRASTRUCTURE FOR A DATA-DRIVEN ECONOMY

Network of data processing facilities

Invest in the **GÉANT** network

Supercomputing **centres of excellence**

Build big data mobile internet through **5G PPP**

Telecoms Single Market for broadband investment



3. DEVELOP BUILDING BLOCKS

Guidelines on standard licences, datasets & charging

One-stop-shop to open data across the EU

Mapping big data standards

Open data **incubator for SMEs**

Training for data professionals

Data market **monitoring** tool



4. TRUST AND SECURITY

EU **Data protection** rules

Guidelines on secure data storage

Consultations on :

- Policy options after **Trusted Cloud** Europe report
- Data ownership & liability of data provision
- User-controlled cloud-based technologies

1) Green Paper – other key issues

Data protection

- Which **security safeguards** could ensure health data is safe in an mHealth context?

Interoperability

- Do you think there is a need to work on ensuring **interoperability** of mHealth applications with **Electronic Health Records**?

Research and innovation

- Could you provide **specific topics** for EU level research & innovation and deployment priorities for mHealth?

1) Green Paper: next steps...

- Consultation period: **10 April -10 July 2014**
- Consultation results and feedback report: expected in **4th Quarter 2014**
- Commission possible policy actions: expected in **2015**

Thank you!

peteris.zilgalvis@ec.europa.eu

Website: <http://bit.ly/EUeHealth>

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