Public consultation on the Commission's Green Paper on mobile health

Fields marked with * are mandatory.

General information on respondents

I'm responding as:*

- ○ An individual in my personal capacity.
- ◉ The representative of an organisation/company.

Is your organisation registered in the Transparency Register of the European Commission and the European Parliament?*

- ◉ Yes
- ○ No

Please indicate your organisation's registration number in the Transparency Register.*

Virtual Physiological Human Institute for Integrative Biomedical Research

Please tick the box that applies to your organisation and sector.*

- ○ National authority
- ○ Regional authority
- ○ Health professionals/medical association
- ○ Non-governmental organisation
- ○ Patients association
- ○ Insurance company
- ○ Manufacturing industry
- ○ App developing business
- ○ Web entrepreneur
- ◉ Other

Please explain the type of organisation/company/business you represent.*

200 character(s) maximum

The Virtual Physiological Human Institute for Integrative Biomedical Research, in short VPH Institute, is an international non---profit organisation incorporated in Belgium, whose mission is to ensure

My organisation/business operates in:*

- ( ) Austria
- (•) Belgium
- ( ) Bulgaria
- ( ) Czech Republic
- ( ) Croatia
- ( ) Cyprus
- ( ) Denmark
- ( ) Estonia
- ( ) France
- ( ) Finland
- ( ) Germany
- ( ) Greece
- ( ) Hungary
- ( ) Italy
- ( ) Ireland
- ( ) Latvia
- ( ) Lithuania
- ( ) Luxembourg
- ( ) Malta
- ( ) Netherlands
- ( ) Poland
- ( ) Portugal
- ( ) Romania
- ( ) Spain
- ( ) Slovenia
- ( ) Slovakia
- ( ) Sweden
- ( ) United Kingdom
- ( ) Other

Please enter your organisation/company name.*

VPH Institute

Please enter your e-mail address.*

manager@vph-institute.org

Please enter your address.*

Celestijnenlaan 300C, 3001 Heverlee, Belgium

Data protection including security of health data

Which specific security safeguards in mHealth solutions could help prevent unnecessary and unauthorised processing of health data in an mHealth context?

- (●) The following security safeguards in mHealth solutions could help prevent unnecessary and unauthorised processing of health data:
- ( ) I don't know.

3,000 character(s) maximum

Legislation already protects unauthorised data disclosure, and normal healthcare processes are required to be conducted in accordance with best practice. However there seems to be no current way in which unwarranted processing of freely-supplied healthcare data can be prevented. It is suggested, for debate, that product certification be considered, to ensure that healthcare recommendations are provided only when warranted by generally-agreed input conditions. ('Generally-agreed' refers to an expert medical consensus). A possibility is that such a mechanism could be voluntary, in the knowledge that lack of such certification would result in consumer product rejection.

How could app developers best implement the principles of "data minimisation" and of "data protection by design, and "data protection by default" in mHealth apps?

- (●) These principles could be best implemented in mHealth apps in the following ways:
- ( ) I don't know.

3,000 character(s) maximum

We are (answer to previous question) proposing a regulatory process in which certification of adequacy is a condition of sale. Part of the certification process could include verification (or self-declaration) that protection and minimisation are established.

Big data

What measures are needed to fully realise the potential of mHealth generated "Big Data" in the EU while complying with legal and ethical requirements?*

- (●) In my opinion, the following measures are needed to realise the potential of mHealth-generated Big Date in the EU:
- ( ) I don't know.

3,000 character(s) maximum

Legal and ethical requirements already exist to protect healthcare data (confidentiality, duty of care, Directive 95/46/EC etc), but there seems to be a lack of control over the extent of data processing and the nature of any authorised data release that might take place. Safeguards have therefore been proposed. Regarding the wider Big Data ambitions of, e.g., the in silico Medicine initiative, as supported by the Virtual Physiological Initiative (VPH) Institute and others, a mechanism for the mass capture of anonymised patient data is required to facilitate this next significant step in healthcare science. We propose (consultation leading to…) a voluntary system under which patients agree to make their anonymised data (or some agreed categories thereof) available for appropriately-controlled central storage and release for approved research purposes (agreement must be reached on the nature of many of the terms used here – anonymisation, controlled, categorisation…). Organisations offering such services would be obliged to implement anonymisation and transfer (or perhaps federation) mechanisms. Consultation is in any case required, to give consideration to the operational and practical frameworks under which centralised data storage, access and refinement could be carried out. As a key component in the eHealth Action Plan (and explicitly endorsed by it) the VPH community, as represented by the VPH Institute, would be an appropriate group to be included, able – as it is – to call upon experts from the EC-backed initiative offering possibly the greatest levels of complexity in current medical technology. In order to ensure compliance with legal and ethical requirements, special consideration needs to be given to the use of medical data in the General Data Protection Regulation currently under discussion by the EU institutions. Access to health data and complete patient registries is crucial in order to have informed health policies and to ensure that health research keeps pace with the health challenges we are facing. It must be ensured in these discussions that the term "data protection" does not become synonymous with "data security". Overly restrictive measures on access to data for medical health research will not make EU citizen's data any more secure but will most certainly impact on the rights of patients to good health. The potential of big data for health itself can only be realised through the uptake of tools, such as provided by the VPH community, that can convert huge quantities of data from a wide variety of fields into information that is understandable for healthcare professionals and patients (personal health forecasting). While huge quantities of data generated in recent years reflect these interactions, such big data in its raw unprocessed form is of no practical use.

State of play on the applicable EU legal framework

Are safety and performance requirements of lifestyle and wellbeing apps adequately covered by the current EU legal framework?*

- ○ Yes
- ○ No
- ◉ I don't know.

Is there a need to strengthen the enforcement of EU legislation applicable to mHealth by competent authorities and courts?

- ○ Yes
- ○ No
- ◉ I don't know.

Patient safety and transparency of information

What good practice exists to better inform end-users about the quality and safety of mHealth solutions e.g. certification schemes?*

- ◉ I know of the following good practice examples of informing users of the quality and safety of mHealth solutions:
- ○ I don't know.

3,000 character(s) maximum

mHealth implies that the users have a degree of information literacy. The disciplined approach to product control already taken by sophisticated vendors, perhaps coupled with a centralised repository of the regulatory data referred to earlier, might provide a comprehensive mSolution. This sidesteps the issue of mHealth illiteracy.

What policy action should be taken, if any, to ensure/verify the efficacy of mHealth solutions?*

- (●) The following policy action(s) should be taken:
- ( ) No action should be taken at present.
- ( ) I don't know.

Please explain why you think so.

3,000 character(s) maximum

Beyond the legislation governing data and devices, it is worth considering issues of design and relevance. And, unless maintained, even state-of-the-art systems will gradually become less relevant to healthcare practice as new discoveries supersede current thinking. The sophistication of a product's design, the significance of its function and its respect for current knowledge can vary substantially, and some means of identifying absolute or relative quality seems desirable. The two factors of regulation and certification are therefore central issues to be addressed. We think that an unregulated market (beyond Data and Device controls) in personal medical data and healthcare-related software is unwise. mHealth products should therefore be subject to a (perhaps voluntary) system of additional assessment and certification. Consultation on this topic should be initiated.

How to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing?*

- (●) The safe use of mHealth solutions can be ensured in the following manner:
- ( ) I don't know.

3,000 character(s) maximum

The above proposal for consultation on regulatory and certification issues deals with efficacy. There is an additional need for consultation on the possibility of mHealth outputs being subject to a system of classification, such that those with potential adverse consequences require an additional reference to a healthcare professional. Tools and technologies provided by the Virtual Physiological Human community can play a substantial role here (having perhaps an in silico mProfessional provide the additional reference mentioned).

The role of mHealth in healthcare systems and equal access

Do you have evidence on the uptake of mHealth solutions within the EU's healthcare systems?

- (●) Yes
- ( ) No

3,000 character(s) maximum

Beyond comparatively trivial but important scheduling systems, in silico mHealth success stories are in their infancy. Examples that have been proposed include: • Automated hormone-monitoring systems (diabetese, thyroid, reproduction...) • Device-centred tracking of accelerated exercise limitation (in e.g. neurodegenerative disease) • Behavioural risk elevation (tendency for elders to fall in adverse weather) • Compliance-monitoring in drug delivery • Social mechanisms for patient support across many conditions • ...

Please upload the evidence you have or paste link(s) to web sources.

What good practice exists in the organisation of healthcare to maximise the use of mHealth for higher quality care e.g. clinical guidelines for the use of mHealth?

- (●) I know the following examples of good practice:
- ( ) I don't know any.

*

3,000 character(s) maximum

There is an absence of controlled standardisation in this field, but many EC-funded Virtual Physiological Human projects (@neurIST, euHeart, VPH-Share, MySpine, VPHOP…) have included processes under which consistent rule-based mechanisms for the use of in silico techniques – arguably highly-sophisticated server-based mHealth solutions) have been developed.

Do you have evidence of the contribution that mHealth could make to constrain or curb healthcare costs in the EU?*

- (•) Yes
- ( ) No

Please explain.

3,000 character(s) maximum

UK appointment-scheduling systems have demonstrated savings that conservatively extrapolate to GBP50M per annum if Virtual Physiological Human technology were to be fully implemented in the UK.

Please upload the evidence you have or provide links to the relevant sources and webpages.

What policy action could be appropriate at EU and national level to support equal access and accessibility to healthcare via mHealth?

- (●) The following policy actions could be appropriate:
- ( ) I don't know.

*

3,000 character(s) maximum

We propose to consider a consumer-group driven initiative to bring together stakeholders, including communications, healthcare, future systems technologists, and researchers. The Virtual Physiological Human Institute will be pleased to participate in this consumer-group providing the technological expertise.

Interoperability

What do you think should be done in addition to the proposed actions of the eHealth Action Plan 2012-2020 in order to increase interoperability of mHealth solutions?*

- (●) I think that the following should be done to increase interoperability of mHealth solutions:
- ( ) I don't think that anything should be done at present to increase interoperability of mHealth solutions
- ( ) I don't know.

Please explain why.*

3,000 character(s) maximum

Interoperability is essential. The VPH community will be amongst the most sophisticated users of this technology and should be included in the consultation process. Decisions should be informed by the US National Information Exchange Model (NIEM). Policy should be formulated now. The Virtual Physiological Human is a European Commission funded initiative that has been specifically endorsed by the European Parliament's 2014 Resolution on the eHealth Action Plan. Support for VPH would acknowledge a political demand by the elected representatives of Europe who in their resolution "Urges the Commission and the Member States to continue working through pilot projects...such as the Virtual Physiological Human initiative in order to develop pan-European interoperability, and to continue to support innovative solutions for person-centred care, including advanced modeling and simulations, needed to achieve the aims of predictive and personalised medicine." This acknowledgement of the European Parliament of the value of Commission backed initiatives shows clear support for a continuation of work being done by VPH and should be supported as part of a comprehensive mHealth strategy.

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

- (●) Yes
- ( ) No
- ( ) I don't know.

If you think so, please explain who should work to ensure interoperability and how should this be done?*

3,000 character(s) maximum

The Virtual Physiological Human community's in silico systems rely on the effective federation of multiple data sources to optimise care. This interoperability is essential. Consultation with the VPH Institute is required

Reimbursement models

Which mHealth services are reimbursed in the EU Member State(s) you operate in and to what extent?*

- ( ) The following mHealth services are reimbursed in the EU country I operate in and this is done in the following manner (please mention the name of the country):
- (•) None are reimbursed.
- ( ) I don't know.

What good practice do you know of that supports the refund of mHealth services e.g. payer-reimbursement model, fee-for-a service model, other?

- (•) I know of the following good practice that supports refunding of mHealth services:
- ( ) I don't know of any such practice.

*

3,000 character(s) maximum

The in silico community is developing mechanisms to enable business cases that extend beyond the bounds of a single reimbursement entity (a hospital, say) to benefit from inputs external to that entity. In other words, downstream (social services) savings can be financially attributed to improved hospital care. In addition, in silico use of cloud services has been implemented via an EC-funded research project to provide an experimental pay-per-use simulation/risk-analysis system (http://vph-portal.eu/).

Liability

What recommendations should be made to mHealth manufacturers and healthcare professionals to help them mitigate the risks posed by the use and prescription of mHealth solutions?*

- (●) The following recommendations should be made:
- ( ) I don't know.

*

3,000 character(s) maximum

Fully representative engagement is required to ensure technical teams across the spectrum of stakeholders are involved. The in silico community should be represented by the VPH Institute.

Research and innovation in mHealth

What specific topics would you provide for EU level research, innovation and deployment priorities for mHealth?*

- (●) I/my organisation would suggest the following topics for research & innovation and deployment priorities for mHealth (please mention the name of your organisation and the sector of your activity)
- ( ) None at present.
- ( ) I don't know.

*

3,000 character(s) maximum

Once more the VPH Institute is the focus for expertise in these arenas. The VPH is an EC funded initiative that has been specifically endorsed by the European Parliament's 2014 Resolution on the eHealth Action Plan as needed “to develop pan-European interoperability, and to continue to support innovative solutions for person-centred care, including advanced modeling and simulations, needed to achieve the aims of predictive and personalised medicine.” We envisage a future where the storage, organisation and processing of data are no longer a computational challenge, and real-time updating of each human’s healthcare avatar is enabling fully-personal simulations to be run continuously, so identifying potential health issues and enabling the environment to be interrogated for personalised threats. The central data repository is aware of every patient’s current health status and investigations are requested automatically if the status so indicates. Diagnosis and treatment options, though ultimately sanctioned by a medical practitioner, are proposed by the software system after multi-disease in silico optimisation. To reach this target in a realistically short timescale, following major topics should be addressed: • Communications (machine-machine & machine-human) • Mobile/fixed and client/server data optimisation • Storage (size, structure, semantics, autoanalysis...) • In silico developments in multiscale, multitemporal, multidisease, multi... • Model reduction approaches • Improved visualisation techniques • The use of HPC and other scalable techniques in routine healthcare • The ICT-optimised hospital We also envisage in silico activities acting beyond the realm of personalised medicine to inform and improve conduct in other healthcare-related • Animal studies/ Massive reduction in experimental animals • In silico clinical trials/ Introduction of simulation to cut costs, time and risk • Human/machine interfaces/ Elimination of unnatural barriers • Total surgical assistance/ Informed planning, guided interventions, optimised post-op Additional investments are needed for research on the question how to make sense of the data collected by mHealth applications in order to arrive at an integrative solution for doctors, patients and industry. For the patient this would be Personal Health Forecasting. A personalized model is constantly adapted with mHealth data and the predictions of this model are used to provide advice and support to the patient. If thousands of patients transmit days of recordings of various sensors, additional developments on in silico technology have to be made to monitor this deluge of data, picking alarming events, observing trends, and derive public health understanding out of it (big data analytics). In silico approaches become vital, from the simplest data mining, to machine learning techniques, but in many cases only a physiology-driven model can make any sense of complex sensor outputs.

How do you think satellite applications based on EU navigation systems (EGNOS & Galileo) can help the deployment of innovative mHealth solutions?*

- ○ I think that satellite applications can help the deployment of innovative mHealth solutions in the following manner:
- ○ I don't think satellite applications can help the deployment of innovative mHealth solutions.
- ◉ I don't know.

International cooperation

Which issues should be tackled (as a priority) in the context of international cooperation to increase mHealth deployment and how?

- ◉ The following issues should be tackled in the following manner to increase mHealth deployment in the context of international cooperation:
- ○ I don't think that increasing mHealth deployment should be tackled in the context of international cooperation.
- ○ I don't know.

*

3,000 character(s) maximum

Internationally the issues relate to differences in standards, and cross-boundary restrictions. A roadmap should be commissioned to identify steps to harmonisation.

Which good practice in other major markets e.g. USA and Asia could be implemented in the EU to boost mHealth deployment?

- (●) The following good practice from other major markets could be implemented in the EU:
- ( ) I don't think any should be implemented.
- ( ) I don't know.

*

3,000 character(s) maximum

The US Food and Drug Administration (FDA) in April 2012 launched “innovation pathway 2.0”. The goal of this initiative was to help those working on innovative medical devices and tools to get to market faster and ensure the uptake of new health technologies. “By engaging with innovators much earlier, more collaboratively, and in new ways, we believe we can reduce the time and cost of the entire process of bringing safe and effective technologies to patients more quickly.” The European Commission should endeavour to increase its collaboration with researchers such as those from the Virtual Physiological Human initiative to ensure that barriers to innovation can be overcome. The European Commission’s idea of “health in all policies” seems to have been abandoned in recent years as is evident by the Proposal for a General Data Protection Regulation, which saw few signs of input from medical researchers. While significant progress has been made with Horizon 2020 in addressing barriers to innovation from FP7, the Commission must ensure that existing projects started under previous frameworks, are not abandoned before they can realize their full potential. The Virtual Physiological Human Institute would encourage the European Commission to follow the theme of innovation pathway 2.0 and its researchers are always open to sharing their expertise to ensure the formulation of balanced and effective health and research policy capable of meeting the multitude of health challenges that Europe now faces.

Access of web entrepreneurs to the mHealth market

Is it a problem for web entrepreneurs to access the mHealth market?

- ○ Yes
- ○ No
- ◉ I don't know.

If needed, how could the European Commission stimulate industry and entrepreneurs' involvement in mHealth e.g. through initiatives such as "Startup Europe" or the European Innovation Partnership on Active and Healthy Ageing?

- ◉ The Commission can stimulate industry and entrepreneurs' involvement in mHealth in the following ways:
- ○ I don't know.

*

3,000 character(s) maximum

We think the commission can stimulate this by furthering the opportunities for academic/SME cooperation, but now extended to favour consortia that include clinical institutions. Project design should allow for large-scale clinical trials of effectiveness for both underlying models of care and implementation mechanisms.

Concluding remarks & references

Please write any concluding remarks you may have that the above questions didn't cover.

3,000 character(s) maximum

Please upload any files with evidence or references that you think the Commision should consider for the effective deployment of mHealth solutions in the EU.