



D4.1 Consolidated Gap Analysis Report

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1 Introduction

This is Deliverable D4.1 “Consolidated Gap analysis report”, produced after the consultation process recalled below, in accordance with the PHS2020 methodology and multi-tier consultation approach¹.

The preliminary draft of the State of play was delivered and discussed on April 4 2008 during the 2nd Experts Support Committee (henceforth ESC) meeting and was revised following the input received.

In parallel to the revision of the State of Play, the scenarios cycle of drafting, consultation and revision was launched using PHS2020 scenarios building methodology and related tools². At the 3rd ESC the very first and preliminary version of the scenarios was discussed and the input of the discussion led to the production of a second intermediate draft.

This second draft of the scenarios was presented and discussed on June 20 2008 at PHS2020 1st Consultation Workshop held in Sheffield. As a result of the input of the workshop a third draft was produced.

This third draft was discussed with Gartner’s analysts, whose input have been used by the project team to produce the fourth draft that was discussed during the 4th ESC meeting and the 2nd Consultation workshops both held in Pisa, respectively, on July 14 and July 15 2008. The input of these two consultation events were incorporated in the final version of the scenarios deliverable mentioned earlier (D3.1 Consolidated Scenario Report).

During the two mentioned events in Pisa, we anticipated the discussion and extraction of gaps from the state of play and the scenarios, as well as the preliminary association of research themes to identified gaps.

On the basis of the preliminary insights and input provided by the experts in Pisa, MIP research team proceeded to the systematic comparison of current developments (D2.1 State of Play) and the foreseen scenarios (D3.1 Consolidated Scenarios Report). This produced the first draft of the Gap Analysis Report, which was presented and discussed during PHS2020 3rd Workshop in Barcelona (26 September 2008). During this event the association of research themes to gaps was also contemplated.

Finally, the list of gaps and research themes emerging from the Barcelona workshop and summarised into the second draft of the gap analysis report were further assessed and discussed during the fifth and final meeting of the ESC held in Milan on October 6 2008.

Starting from the wide analysis of the state of play the project has been gradually zooming closer to the final expected outcome of proposing a few roadmaps for research themes to be funded in FP7 and beyond. This has implied a progressive reduction of complexity and selection of key issues and topics. In particular from the first draft of the gap analysis to this final draft, through the input of the Barcelona workshop and the 5th

¹ For an illustration of the overall methodology and multi-tier consultation approach see PHS2020 Deliverable D2.1 *State of Play*, pp. 8-11. All PHS2020 deliverables can be downloaded at: http://www.phs2020.com/index.php?option=com_content&task=category§ionid=7&id=21&Itemid=27.

² See PHS2020 Deliverable D3.1, *Consolidated Scenario Report*, § 2

ESC meeting, we have moved from the **Full List** of 54 gaps (see Table 1, Table 2, Table 3) to a **Short List** of about 20 of them (see Table 4), which have been further synthesised and grouped into five domains of research already associated preliminary proposals of research themes (see Table 5). The final ESC meeting helped in consolidating the gaps analysis, as the shorted list was re-assessed, validated and commented by the experts, so that it was subsequently refined. The final summary of all the gap analysis work and consultation cycle presented in Table 5 and commented in § 4.3, will serve as the platform for the final two consultation events focussing on the final roadmaps (PHS2020 4th Workshop, Brussels 21 November 2008; PHS2020 Final Conference, Brussels, 5 December 2008).

Besides the research roadmaps, one of the project expected output was to come up with a consensus of what PHS is and what it is not. Identifying clear boundaries for PHS is challenging, and cannot be done by the research team alone. On the contrary, the elaboration of a shared definition of PHS is a collaborative and iterative process, involving MIP research team, the European Commission, the experts composing the ESC, and those experts and stakeholders taking part in project consultation events. In each occasion, in fact, a working version of the PHS definition is presented and discussed, and inputs elaborated to improve it. In view of the above elements and discussion the following definition of PHS has been drafted, that will be presented to stakeholders to further discussion and refinements:

Personal Health Systems (PHS) assist in the provision of continuous and personalised health services to individuals regardless of location. They consist of:

- a) *Wearable, portable or implantable devices, which acquire, monitor and communicate physiological parameters and other health related information of an individual (related to e.g., vital body signs and biochemical markers);*
- b) *Intelligent processing of the acquired information and coupling of it with expert biomedical knowledge to derive important new insights about individual's health status.*
- c) *Active feedback based on such new insights, either from health professionals or directly from the devices to the individuals, assisting in diagnosis, treatment and rehabilitation as well as in disease prevention and lifestyle management.*

With the completion of the gaps analysis consultation cycle, PHS2020 has entered into the final phase where the large amount of data and information gathered and analysed has to be turned into the final road map. This phase is of strategic importance for the successful completion of the project and more broadly for providing a useful input to the community of interested stakeholders and experts in the form of a roadmap of future research themes in the field of PHS. At this stage the input from experts in the remaining contribution events is key to validate and improve the analysis and proposals being formulated by MIP team. The remaining consultation events are the following two:

- The 4th Consultation Workshop to take place in Brussels on November 21, 2008;
- The final conference on PHS2020 vision and roadmap to take place in Brussels on December 5, 2008.

Chapter 2 illustrates the methodology we applied to extract the identified gaps through a systematic comparison between the state of play and the scenarios. The large list of 54 identified gaps is presented and commented synthetically in **Chapter 3**, where we also briefly explain the assessment carried out during the Barcelona workshop and present the

resulting shortlist of the most important and relevant gaps. In the conclusive **Chapter 0** for the shortlist of gaps we present a storyline and associate a preliminary set of research themes, which are then also conceptualised into areas of research. In **Annex I**, finally, the procedures and elaborations done for gap assessment are illustrated.

2 Gap analysis methodology

2.1 Understanding gap in the PHS2020 context

The application of gap analysis to the context of PHS and the discussion that follows is an adaptation of the approach successfully developed in the FP6 project eGovRTD2020 in the roadmapping of future research for eGovernment (Codagnone and Wimmer 2007)³.

In its traditional and original application gaps analysis is above all a strategic management tool, and is performed comparing the ‘as is’ to the normatively defined ‘to be’ status one aim to shape and reach. Thus a gap is simply the difference between the ‘as is’ and ‘to be’ and, given the clear cut and to some extent deterministic way in which the ‘to be’ is conceived, can be assessed in a fairly objective and straightforward fashion.

Given our overall approach to foresight, with the indeterminate vision of the future as possible alternatives defined in the scenario-building step and the various complexities and uncertainties that this entails, our understanding of a gap cannot be as simple and straightforward as in the case of traditional strategic management gap analysis.

PHS2020 is inscribed in a comprehensive framework that conceives of the PHS domain as a complex and dynamic socio-technical system and as such deals with both broad visions and detailed analyses. The scenarios developed provide a set of internally coherent but alternative visions of the future introducing high uncertainties and the possibility of very radical and complex changes. In this context the simple and automatic operation: SCENARIOS – STATE OF PLAY= GAP is not applicable.

Gaps analysis in our context entailed looking at major discontinuities, unknowns, and contrasts between the situation today (examined in the state of play) and the possible futures as envisioned in the scenarios. In our approach *a gap expresses a mismatch that emerge through a systematic comparison between the state of play and the envisioned scenarios clustered around the key dimensions of PHS2020 General Descriptive framework*. A gap may thereby refers to an issue of current research (identified in the state of play), which does not meet the needs identified by one or more of the future scenarios, or by trends that are horizontal and cross-cutting to all of the scenarios. A gap may also refers to an issue, which is not addressed at all by current investigations and not captured in the state of play, but emerged in the scenarios, or more broadly to discontinuities and unknowns not necessarily deriving from contrasting state of play and scenarios. So gaps in our approach are not simply and strictly defined differences

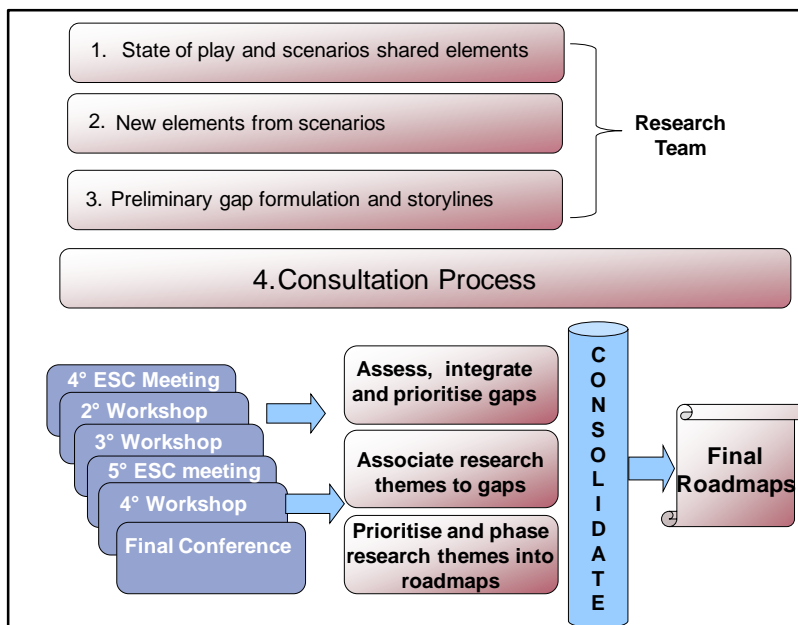
³ See in particular within the final eGovRTD2020 book : Pucihar, Bogotaj and Wimmer (2007) and Pucihar, Bogotaj, Wimmer and Janssen (2007). The eGovRTD2020 gap analysis methodology was based on a review of the relevant literature (mostly from the management discipline) from which the elements applicable to the context of policy oriented roadmapping were extracted. In this paragraph we strictly follow this discussion with slight adaptation to the PHS2020 context. Accordingly for the background literature on gap analysis the reader can consult the cited chapters in the eGovRTD2020 book (still available digitally at: <http://www.egovrtd2020.org/EGOVRTD2020/FinalBook.pdf>) and we do not repeat such review here.

between the ‘as is’ and the ‘to be’ status; rather they encompass different issues than can emerge by a broad comparison of the state of play with the alternative possible futures elicited by the scenarios.

2.2 Gap analysis steps

The various steps illustrated in the Figure 1 are briefly explained below. As scenarios were not an end in itself but instrumental to the successive steps of the project, in the same way the identification of gaps was done from the very beginning not as a self-contained task but with the clear goal of uncovering research needs.

Figure 1 Gap analysis and roadmapping steps



Source: Authors’ elaboration

In a way, though separated conceptually and also in the breakdown of our project activities and consultation events, gaps analysis and roadmapping are tightly entwined. Naturally this deliverable stops at the end of the gap analysis cycle and provides the input for the next one on final roadmapping that will take place during the next two consultation events (PHS2020 4th Workshop and Final Conference)

Step 1 – Identification of common issues between the state of play and the scenarios, where current research will not meet future challenges, or where current research needs to be continued to meet them. Common issues are generally the source of gaps calling for continuation and deepening of research themes that *have been already* funded by the Commission in the domain of PHS within FP5, FP6 and FP7.

Step 2 – Identification of lacking issues, which are not mentioned in the state of play but emerged in the visionary scenarios for 2020. These lacking issues are generally the source of gaps calling for research directions that *have not been so far* funded by the Commission in the domain of PHS within FP5, FP6 and FP7.

Step 3 – Preliminary gap formulation and storylines, the issues identified in step 1 and 2 were formulated a complemented with a storyline to convey the problem scope of gaps

and their implications in terms of needed research themes, which are preliminarily formulated.

2.3 Gap assessment: consultation process

The first three steps illustrated in Figure 1 were carried out by the research team on the basis of the validated and consolidated versions of the state of play and of the scenarios reports and produced a first preliminary list of gaps with their storylines and preliminary research themes, which became the platform for the subsequent gap analysis consultation cycle.

First, during the 4th ESC Meeting (Pisa 14 July 2008) and the 2nd Consultation Workshop (Pisa, 15 July 2008) this preliminary list was further fleshed out producing a large and comprehensive list of 54 Gaps (see **Table 1**, **Table 2**, **Table 3**, pp. 10-15). A preliminary assessment and prioritisation of the gaps was also performed during these two events.

Second, during the 3rd Consultation Workshop (Barcelona 26 September 2008) and the 5th ESC meeting experts and stakeholders were asked to assess the gaps list produced as a result of the two earlier cited events⁴. During these consultation events the experts were asked to assess the gaps with respect to two dimensions:

- **Type of action needed** for filling the gap to be chosen among:
 - Technological R&D themes that can be funded within the Commission FP7 and beyond;
 - Broadly defined implementation / deployment issues clearly of a non technological socio-economic nature, and/or related to technology but falling outside the strictly defined PHS domain of research (i.e. interoperability)
- **Importance** of the gap for the future development of PHS, on a scale from 1 to 5 (where 1 was the lowest and 5 the highest level of importance).

During the cited consultation events, beside the assessment of gaps, the experts were also asked to start associating to the identified gaps research themes and issues for implementation and deployment and to discuss their view on the gaps and the associated research themes. Accordingly, in addition to the assessment and validation of the list of gaps, we also obtained valuable input to: a) rephrase and/or merge overlapping gaps (see explanation in § 3.3); b) streamline and make the gap storylines more effective (see gaps boxes 1 through 20 and text illustration in § 4.2); c) provide a first synthetic grouping of gaps into five domains of research with associated research themes (see **Table 5**). All of this provided the platform on the basis of which the last two consultations events devoted exclusively to the production of the roadmaps will be run in the coming months (4th Consultation Workshop Brussels 21 November 2008; Final Conference, Brussels 5 December 2008).

⁴ A more detailed explanation of the assessment procedure is in Annex I.

3 PHS2020 Gaps: overview and restricted list

In the paragraph 3.1 we illustrate the gap presentation framework and in paragraph 3.2 we report the full list of 54 gaps. Finally in paragraph 3.3 the results of the assessment procedure carried out during consultation events (Consultation Workshop in Barcelona and the 5th ESC meeting) are presented, in the form of the shortlist of most important and relevant gaps.

3.1 *Illustration of the gaps presentation framework*

In undertaking the systematic comparison between the state of play and the scenarios we used as a structuring conceptual tool the same “General Descriptive Framework” used for the scenario building, and we filled it in by systematically comparing the state of play and the scenarios. This Descriptive Framework has been schematically reported below with some adaptations and terminological changes with respect to the original version that have been determined by the results of the gap analysis:

- Macro socio-institutional environment:
 - Society (dimension):
 - Demography and health situation (sub-dimension);
 - Rise of chronic diseases (issue)⁵;
 - Economy;
 - Governance;
- Transactional environment:
 - Healthcare professionals (dimension);
 - Awareness (issue);
 - Healthcare delivery;
 - Third party payers;
 - Industry;
- Users and PHS:
 - Awareness, trust, access and use;
 - Comfort, acceptance, personalisation.

Evidently the various dimensions of this framework can be separated only conceptually, for in reality they are closely inter-connected and interacting with each other. It goes without saying, thus, that gaps placed under one dimension of our framework, could as well be relevant for another one and there are probably some overlapping among gaps. In some of the cells of the mentioned three tables we added some cross-references and, at any rate when we moved from the larger list to the restricted one and from this to the aggregation of gaps into research domains overlapping gaps were merged and streamlined. Each of three tables deals with one category of the descriptive framework and disaggregates the categories into dimensions and their corresponding issues. Next to each issue there is a brief narrative that qualifies it and illustrates its relation to the current developments (state of play) and the scenarios. Moving right from the issues the formulation of gaps follows.

⁵ Notation added and not repeated for the other components of the framework in this list

3.2 Snapshot of identified gaps

Table 1 Gaps full list: Macro Environment

Dimensions	Issues	Current developments/ scenarios	GAPS
Society: demography and general health situation	Rising Chronic diseases prevalence	Trend already evident and addressed by advanced research applications but only by basic market services. Cross-cutting all four scenarios, a challenge particularly for “State keeps on trying”.	1. PHS have yet little market penetration; 2. PHS sensors still miss calibration, optimised power supply, multiples signs per sensor, actuation, multi-modal analysis and fusion;
	Co-morbidities of chronic disease implication for both management and early detection	Not addressed in currently available market and research applications. It emerged during the consultation process. Cutting across the scenarios but particularly salient in “Self-caring Society” (management) and in “The Caring State” (early detection) ”	<u>Integrated care processes and delivery</u> 3. Little integration of care delivery processes 4. Knowledge and information segmented ; 5. Lack of shared platform for data repository and exchange; N.B. Not repeated elsewhere but relevant in many other dimensions
			<u>Disease management</u> 6. Inefficient energy and bandwidth use ⁶ 7. Lack of multi-signs/ multi-disease sensors
			<u>Early detection</u> 8. Encompassing biomarkers per lab-on-chip are limited to 2-3 9. PoC sample handling and preparation still, in most cases, requiring human intervention 10. Time to result is still too long
	Long-term care	The need to assist the elderly will increase even in absence of acute and chronic situation. Independent living research addresses this, but more efforts are needed. Particularly salient for State keeps on trying	11. Need of holistic PHS rehabilitation solutions; 12. Need of holistic PHS monitoring solutions
Neuro-psychological disorders	These diseases are only starting to be addressed in PHS. Cutting across all four scenarios.	13. Lack of research on how to acquire data on emotional status and social interaction	

⁶ Insufficient integration of sub-systems resulting in high bandwidth requirement and power consumption (data gathering and processing separated -> large amount of data to be inter-communicated).

Society: Cultural attitudes and inclusion issues	ICT supported health consumerism	Springing from the “Self-caring Society”: more personalisation, participation to treatment decisions, ownership of data, etc	14. Need to prepare healthcare professionals for more symmetric relations with citizen/ patients • See also governance and transactional environment and also Users & PHS
	Moral hazard and fatalism	Attitude present today and a challenge for “Caring State” scenario if they persist	15. Need of cogent incentives backed by sanctions
	Low confidence in/access to ICT	Evident today but basically related to “Two-tier healthcare management” and “State keeps on trying” scenarios	16. Need of education campaign and integration between eHealth and eInclusion policies (see more in Table 3 on Users & PHS)
Economy	Energy crisis	Emerged in the consultation process and relevant under a scenario of large scale adoption of PHS such as the “Self Caring Society”.	17. Need of energy efficient PHS sub-systems and components
	Environmental sustainability	Emerged in the consultation process and relevant under a scenario of large scale adoption of PHS such as the “Self Caring Society)	18. Need to reduce PHS waste and disposal
Governance	Standard and rule setting (steering)	Fragmentation in legal frameworks (privacy, access to data, responsibility) inter-operability, guidelines, in brief lack of high level steering.	19. Lack of clear legal framework 20. Lack of bodies setting binding standards on inter-operability, protocols, pathways and clinical guidelines and stakeholders fora (including industry) at both national and EU level See more under Industry
	Financing	Current systems not sustainable, from Self-caring scenario springs the idea of outcome based financing	21. Institutional reform (see more in Table 5: 3rd party payers)
	Prevention & Compliance Focus	Little money currently allocated, issues stressed under “Caring State”, but relevant to mitigate risk in “Self-caring society)	22. Need to increase investment of public funds

Table 2 Gaps full list: Transactional Environment

Dimension	Issues	Current developments/ scenarios	GAPS
Healthcare professionals attitudes/needs	Awareness/skills	State of play evidenced lack of awareness	23. Awareness campaigns, education, training
	Confidence in the scientific reliability of PHS applications	Clinicians in relation to ‘Self-caring society’ scenarios stressed: <ul style="list-style-type: none"> • Need of scientific control of PHS; • Need of risk profiling to select target for use of PHS (especially for early detection and prevention) 	24. PHS not fully informed by clinical evidence, and by molecular and genetic data
	Patient safety	Concerns about long term effects for human body contact with, ingestion of, sensors voiced by clinicians especially in relation to ‘Self-caring society’.	25. Lack of data on long-term effects of contacts between human body and sensors of different materials especially for implantable (e.g., toxic effects)
	Decision support & guidance	Issue raised by clinicians in relation to ‘Self-caring society’ (decision support to interact with empowered citizens) and for the Caring state (top down pathways and guidelines)	26. Need of innovative DSS for healthcare professionals based on prediction/simulation/visualisation 27. Need of PHS systems embedding clinical guidelines and pathways holistically ⁷
Healthcare Delivery and PHS	Integration of patients’ data	Little achieved in practice, potentially addressed by research but no deployment. Barriers are related to fragmentation of care processes, legal frameworks, interoperability Cross-cutting all scenarios.	28. Lack of shared infrastructures and standards for data exchange 29. Lack PHR inter-operability even at national level, gap relevant also for industry
	Prevention	Market applications are limited to basic fitness focussed services. Lifestyle and prevention research projects have been financed by FP, but they show less advancement compared to chronic disease management. Current reimbursements models provide little incentive. In the Caring state scenario prevention is one of the key characterising elements	30. Lack of business model 31. Lack of consolidated evaluation methods and supporting evidence ⁸

⁷ Software systems to coordinate the activities of all the health professionals responsible for the treatment of a patient and aligning delivery to best practice guidelines.

⁸ Need to build evidence-based PHS prevention services linking PHS data with centrally stored health status indicators, by way of secure communication infrastructure.

Dimension	Issues	Current developments/ scenarios	GAPS
	Early detection, screening and profiling	Detection, screening and profiling are salient for the Caring state scenario	32. Lack of large enough databases for genetic mass screening of population 33. Need of legal framework and consensus
	Compliance	The importance of compliance with prescribe treatment and medication (especially for the elderly) and with life-style guidance (for all) is underscore in the scientific literature, but no products/services are available in the market and the research solutions are still basic (Automatic medication dispensers with certain alarm functions; developments in constant monitoring with wearable solutions) Compliance is key to the Caring State scenarios, but as a risk mitigating factors in light of citizen empowerment also in Self-caring society and Two tier healthcare management	34. Alarm functions and reminders are patently insufficient to ensure compliance 35. Need of closed loop solutions monitoring dispensation/reaction calling for all encompassing sensor 36. Need of more comfortable and less invasive sensors
3rd Party Payers	Outcome-based reimbursement	Large debate on how to increase efficiency and effectiveness of healthcare expenditure and create incentives for PHS. Widely recognised that lack of business model is a main barrier. This innovation is envisioned in “Self-caring society” and “Two-tier healthcare management”	37. Need of innovative measurement systems to support outcome based reimbursement based on integration between PHS generated data and larger public health data bases
Industry Perspective	standards / privacy and legal framework / interoperability	These issues are clearly documented in the state of play and have already been included in Table 1 (Governance). Industry representatives consulted during workshop sees these creating local rather than Pan-European markets and as the key barriers (relevant for all scenarios). In next cell only the technological gaps are indicated (but it is clear that until these governance issues are not solved, technologies will find difficulties to be deployed)	38. Lack of tailoring of security and encryption techniques for healthcare sector application 39. Need of data management and mining applications integrated into PHS that embed, support and protect privacy (also relevant for Users & PHS, will not be repeated)

Table 3 Gaps full list: Users and PHS

Dimension	Issues	Current developments/ scenarios	GAPS
Awareness, trust, access and use	Awareness and trust	All these three sub-issues concerns a situation already evident today but that could become exacerbated in the “State keeps on trying” and “Two tier healthcare management”, namely social divide with respect to awareness and trust, access, capacities to effectively use. They have been strongly emphasised by experts during consultation process. Naturally the solutions to these gaps will benefit also more sophisticated users (so are relevant also for the other two scenarios)	<u>Information campaign</u> 40. Off and online information (on scientific reliability, privacy issue, benefits, etc)
	Access		<u>More widespread and accessible channels</u> 41. Lack of PHS services delivered through Digital TV ⁹
	Interfaces/interaction		Currently little has been done in terms of educational campaign, systematic provision of scientific reliable information, more accessible solutions, optimised interface, tools (imaging, visualisation) multi-modal interaction (mostly one-way messaging and little two-way interaction with functionalities resembling face2face interaction)
Comfort, Acceptance, personalisation	Comfortable devices for acceptance	Efforts toward miniaturisation are visible in research and were considered of strategic importance during consultation process. Cross-cutting all four scenarios	45. Lack of “soft” and “invisible” devices that, however, ensure reliability of data gathered (i.e. wearable)
	Implantable	Implantable are an emerging issue in PHS research and, besides evident legal implications, raise serious issue of users acceptance and safety that were considered of strategic importance during consultation process. Cross-cutting all four scenarios	46. Implanted sensors gather data and actuate but do not communicate and cannot be monitored
Comfort, Acceptance, personalisation	Personalisation	Theme emerging mainly from Self-caring scenarios (see narrative about ICT supported healthcare consumerism). The issue of self-adaptivity and of multi-signs data gathering, however, was already clear from the state of play and is relevant not only more sophisticate consumerist users but also for all other segments of users	47. Need of auto-adaptive algorithms autonomously adjusting clinical parameters to individuals’ conditions 48. Need of sensors monitoring different kind of signs ensuring context awareness 49. Development of modelling techniques able to correctly link physiological signs and motions, gestures, environmental data

⁹ (Way more diffused among the elderly and other less technologically sophisticate segment of the population and more intuitive than other channels.

Dimension	Issues	Current developments/ scenarios	GAPS
			<ul style="list-style-type: none"> 50. Need of ubiquitous services distributed across territory and of large processing capability into small and easy to carry/wear devices 51. Need of intuitive patient decision aid tool (prediction and simulation) 52. Need of quality controlled web 2.0 tools 53. Need of citizen owned fully inter-operable Personal Health Records (PHR) integrated with PHS 54. Possibility to adapt PHS components (e. g., sensors) according to individuals' characteristics, including, materials (due to allergies, for instance), position on patients' body, etc

3.3 Assessment of Gaps

The full list of gaps presented earlier was assessed by experts to produce a restricted and more manageable list containing gaps that met both these two criteria: a) high importance; b) related to needs of technological research¹⁰.

As a general consideration, it is possible to notice that very few gaps have been considered of low importance and were only slightly below the threshold of 3.5 (only 7 out of 54). In addition, several of the identified gaps received a high score on importance, but were considered as implementation issues (23 out of 54)¹¹. These gaps associated to implementation issues will not be further considered in the process of building the roadmap, which will focus only on the gaps related to need of technological research. They represent, however, an important input that will be later discussed in one of the chapters of PHS2020 final book (upcoming deliverable D6.2).

Out of the 31 gaps associated to technological research few have been discarded outright because of having low importance, but several of them have been merged. Indeed, as we anticipated, the consultation events were not used only to get from experts a score on the gaps but also to discuss and possibly re-elaborate some of the gaps. Combining the assessment with the proceeding of the brainstorming discussion recorded and analysed after the consultation events, the short list of 20 gaps contained in Table 4 overleaf. Six gaps were merged to six main ones kept in the short list, six were discarded (but are nonetheless reflected in the short list) and one new gap originally not present in the full list of 54 gaps was added. We briefly illustrate here the merged gaps and those eliminated.

Gap 36 “Need of more comfortable and less invasive sensors” and Gap 45 “Lack of ‘soft’ and ‘invisible’ (i.e. wearable)” are now to be seen as sub-issues of Gap 54 “Low possibility to adapt PHS components to individual characteristics” (now # 8 in the short list of Table 4), as it can be seen from Box 8 at page 29.

Gap 41 “Lack of PHS services delivered through Digital TV” is now to be seen as a sub-issue of Gap 44 “Need of new technological solutions enhancing development and implementation of multi-channel interaction systems” (now # 11 in the short list of Table 4), as it can be seen from Box 11 at page 31.

Gap 13 “Lack of research on how to acquire data on emotional status and social interaction”, which was specifically conceived with regard to the lack of PHS application for neuro-psychological disorders, is now to be seen as a sub-issue of either Gap 48 “Need of sensors monitoring different kinds of signs ensuring context awareness” (now # 7 in the short list of Table 4) or Gap 7 “Lack of multi-signs/multi-disease sensors” (now # 14 in the short list of Table 4), as it can be seen from Box 7 at page 28, and from Box 14 at page 33.

Gap 46 “Implanted sensors gather data and actuate but do not communicate and cannot be monitored” together with Gap 2 should be now considered as forming the re-

¹⁰ See illustration of gap assessment procedure and of its main results in Annex I: Procedure for gap assessmentAnnex.

¹¹ These are gaps 1,3,4,5,14,15,16,19,20,21,22,23,28,29,30,31,32,33,37,38,39,40,53 of those in the full list of gaps.

formulated Gap “Lack of Actuators” (# 15 in the short list of Table 4), as it can be seen from Box 15 at page 34.

Table 4: Short list of gaps

Gaps	Reference to larger list /comments
1. Lack of integration of clinical evidence, and of bio-medical and genetic information	# 24 of full list
2. Need of auto-adaptive algorithms autonomously adjusting clinical parameters to individuals' conditions	# 47 of full list
3. Need of PHS systems holistically embedding clinical guidelines and pathways	# 26 of full list
4. Lack of monitoring techniques able to correctly link physiological signs and motions, gestures, and environmental data	# 49 of full list
5. Need of innovative and holistic DSS for healthcare professionals based on prediction/simulation/visualisation	# 27 of full list
6. Need of imaging and visualisation techniques for intuitive and easy to interpret input	# 43 of full list
7. Need of sensors monitoring different kinds of signs ensuring context awareness	# 48 but also reflecting # 13 (emotional status) of full list
8. Low possibility to adapt PHS components to individual characteristics	# 54 but also partially reflecting # 36 (implantable) and # 45 (wearable) of full list
9. Lack of data on long-term effects of contact between human body and sensors	# 25 of full list
10. Need of PHS embedded eLearning	# 42 of full list
11. Need of new technological solutions enhancing development and implementation of multi-channel interaction systems	# merge of 41 and 44 of full list
12. Need of quality controlled Web 2.0 tools	# 52 of full list
13. Need of intuitive patient decision aid tools (prediction and simulation)	# 51 of full list
14. Lack of multi-signs/multi-disease sensors	# 7 but also reflecting # 13 (emotional status) of full list
15. Lack of actuators	Derived from # 2 and also reflecting # 46 (implantable and actuation) of full list
16. Personalised drug delivery and compliance	Merging # 34 and 35 of full list
17. Endoscopy capsules	New added gap
18. Encompassing biomarkers per Lab-on-Chip are limited to 2-3	# 8 of full list
19. PoC sample handling and preparation still, in most cases, requiring human intervention	# 9 of full list
20. PoC: time to result is still too long	# 10 of full list

Gap 34 “Alarm functions and reminders are patently insufficient to ensure compliance” and Gap 35 “Need of closed loop solutions monitoring dispensation/reaction calling for all encompassing sensor” have been merged into the reformulated Gap “Personalised drug delivery and compliance” (now # 16 in the short list of Table 4), as it can be seen from Box 16 at page 34.

The new Gap “Endoscopy Capsules” (# 17 in the short list of Table 4) has been added and is illustrated in Box 17 at page 35.

The six gaps eliminated as a result of the experts’ assessment were the following:

- # 6 “Inefficient energy and bandwidth use¹²”;
- # 11 “Need of holistic PHS rehabilitation solutions”;
- # 12 “Need of holistic PHS monitoring solutions”;
- # 17 “Need of energy efficient PHS sub-systems and components”;
- # 18 “Need to reduce PHS waste and disposal”;
- # 50 “Need of ubiquitous services distributed across territory and of large processing capability into small and easy to carry/wear devices”

They were not included in the short list, not only because they received a score in terms of importance below 3.5, but also because they were deemed already reflected by other gaps.

Gaps # 6, 17 and 18 about energy efficiency and reduction of waste disposal are addressed now both by the gaps about the low adaptability of sensors and the need of multi-signs / multi-disease sensors, for they both point to the need of networks of sensors reducing the number of components and the need to reduce transfer of data (also by developing on board processing capabilities in sensors) as illustrate in Box 8 at page 29 and in Box 14 at page 33.

Gaps 11 and 12 about holistic rehabilitation and monitoring solutions are to some extent reflected by the gap about lack of actuators (see Box 15 at page 34) and about personalized drug delivery (see Box 16 at page 34). Moreover, the research themes associated to the gaps on low adaptability of sensors and the need of multi-signs / multi-disease sensors also envisage holistic monitoring solutions. These same holistic solutions capture also the implications of Gap # 50.

Finally, it is worth recalling that already in the state of play we signalled how most PHS disease management solutions focused on cardiovascular and respiratory diseases and on diabetes and that there is a need to expand the reach into other diseases, of which we particularly mentioned neuro-psychological disorders. The latter is now reflected in the gap about the need of multi-signs/multi-disease sensors. In a way the expansion of sensors capability in terms of sign captured will make possible to include within the reach of PHS also other disease beyond those currently most commonly addressed.

4 From gaps to research themes

In this chapter the restricted list of 20 gaps is further analysed and put into context of further research, paving the way for roadmapping. General considerations going beyond the identified gaps are reported in paragraph 4.1. In paragraph 4.2, each gap of the final restricted list is described with more details. The research items and enablers identified in

¹² Insufficient integration of sub-systems resulting in high bandwidth requirement and power consumption (data gathering and processing separated -> large amount of data to be inter-communicated).

gaps analysis are then re-organised into research domains in paragraph 4.3, as a preparatory step for roadmapping. Finally, in paragraph 0, some hints about the final roadmap, and the methodology to build it are presented.

4.1 “Meta-gap”

Besides the short listed gaps calling for technological research, both some of the 23 implementation gaps and the general discussion taking place during the consultation events point toward what we could call a ‘meta-gap’ concerning clinical validation and inclusion of the clinical expertise in PHS project funded with the Commission Framework Programmes.

The clinical validation of PHS projects, both in terms of clinical magnitude and cost-benefit outcomes, was discussed in all the consultation events. Consensually, workshop attendees and ESC members agreed on that it is of major and key importance to include validation of PHS technologies in real environments into research programmes, starting from next FP. Although, it is acknowledged that it is very difficult to include large clinical trials due to the fact that it is not affordable with current budgets, in addition of it not being within the context of current FP framework. However, what is considered to be executable within the scope of current and future Framework Programmes is an in-deep evaluation of the technology, in order to verify its objectives. This requires less number of participants than full clinical trials, but could provide a solid basis for such. Additionally, validation can also be obtained by involving clinicians at an earlier stage than normally is the case in current research projects. It is further suggested that proposals involving clinical parties (including the whole spectrum; e.g. nurses, personal trainers, behavioural and sociological scientists etc) could obtain higher scores, thus increasing the “incentive mechanisms”.

4.2 Gaps storylines

In this paragraph we report, for each of the 20 gaps of the **Short List**, summary boxes structured as illustrated below.

Name of the Gap	
Rationale	Which problem the gap hints at
Research items	PHS specific research themes preliminarily associated to the gap
Overlaps/ complementarities	Research themes, associated to other gaps, that overlap and/or are in a logic relation of complementarity
Other	See explanation in text below

Under the heading “other” are included themes that are relevant to fill the gap but either point to matters of implementation (i.e. inter-operability) or concern technological and non technological research development falling outside the traditionally defined scope of PHS or not driven by PHS. An example could be MEMS and NEMS¹³ that have been and

¹³ Micro-Electro-Mechanical Systems (MEMS) and Nano-Electro-Mechanical Systems (NEMS) based sensors represent technological advancements being developed in other domains but with clear potentiality for PHS. They have been treated briefly in deliverable D2.1 State of Play. Here it suffices to say that they may enable the implementation of micro-level systems interacting with their physical environment, minimally invasive, integrating sensing, computation

are being developed in other fields but could enhance also PHS future applications. The two sections of the boxes “Overlaps/complementarities” and “Other” are included only for the gaps for which they apply. We must underline that, whereas all other sections of the summary boxes simply reflect the input obtained from experts during the workshop, that on “Overlaps/complementarities” (see more in § 4.3) results from our ex post comprehensive reading of all the 20 short listed gaps.

Each box is referenced only with a short version of the name and with reference to its number in the **Full List** of gaps. Following mentioned snapshot, more in-detail description is given both for the gap and in the stories, which further exemplify the technological challenges to be met, and thus potential effects they can have on the development of future PHS solutions.

Box 1 Integration of clinical evidence and genetic information (# 24 of Full List)

Lack of integration of clinical evidence, and of bio-medical and genetic information

Rationale	<p>Today PHS are mostly limited to vital and physiological signs and the processing thereof, which results in limited assessment and treatment and in the need of continuous traditional medical interventions.</p> <p>In brief: PHS analysis is too general and hence very limited in terms of holistic cause-effect analysis => Need to Include all relevant macro and micro medical information necessary to run a whole and complete assessment of each individual’s health status. Filling this gaps also contribute to make Personal Health System more “Personalised”.</p>
Research items	<ul style="list-style-type: none"> • Integration into PHS of up-to-date medical information from bio-banks, clinical trials; • Integration into PHS of genetic and biomedical information;
Overlaps/ complementarities	<ul style="list-style-type: none"> • See Box 2 for the need of integrated interpretation and processing of genetic, biological and contextual data and for the challenge of data gathered under “uncontrolled conditions”
Other	<ul style="list-style-type: none"> • Ongoing investigation on linkage between genotyping and phenotype in pathologies; • Insights from chrono-biology (science that examines periodic, cyclic phenomena in living organisms and their adaptation to solar and lunar related rhythms);

Gap description

This gap was elicited by “Self-Caring Society”(users highly empowered and acting independently of helathcare professionals intervention) “Caring State” (massive use of PHS for prevention and early detection) scenarios, where a large scale adoption of PHS is envisaged. This led experts to stress that a) PHS should be scientifically controlled and reliable b) a filter should be used to select individuals to be targeted by PHS for prevention and early detection in the form of risk profiling. The implication being that PHS need to integrate, and being informed by, clinical evidence and molecular and genetic information.

and actuation, capturing several signs and possibly increasing energy efficiency and decreasing bandwidth requirements.

Today PHS are mostly limited to vital and physiological signs and the processing thereof, which results in limited assessment and treatment and in the need of continuous traditional medical interventions. In order to realise a future where users are fully empowered and can achieve concrete outcomes in various ways (not only monitoring, but also in diagnosis, treatment, early detection and prevention, lifestyle management) directly from PHS services the latter by necessity must be based on clinical evidence and bio-medical and genetic information.

Gap Storyline

As clinicians participating to PHS2020 Barcelona Workshop affirmed, it is common wisdom that what we are and our health conditions are jointly shaped by our genetic endowment and by environmental factors. Thus, if we match vital and physiological signs with genetic information and also with contextual aspects (environmental and emotional factors) patterns can be identified useful for treatment and/or prevention. For instance, genetics can be used to molecularly diagnose a disease (i.e. cystic fibrosis depends on the mutation of one gene) and accordingly prescribe to most appropriate treatment. Hence, the genome holds numerous information with implications on one's health and for prevention. From a clinical and clinicians' point of view, it is interesting looking at phenotyping diseases in order to address and customise strategies for the patients. This means that there needs to be some interaction between different disciplinary clinical and non-clinical professions, in order to include predictions into supporting tools. In this respect we see the potential and need for convergence between PHS and biomedical informatics research. In the timeframe of our roadmaps, it will probably be possible to have the personal genome in a few hours and at low cost. This fact is of major importance considering that the combination between dynamic (phenotypic) and static (genotypic) values opens significant personalisation opportunities. Naturally, in order to harvest the full potential of genetics into PHS, more links to phenotype is needed, i.e. further investigations are needed to assess the connection between genetics and certain pathological conditions.

Finally, in order to increase the personalisation of PHS through integration of the kind of evidence and information discussed so far, the cross-combination of genetic and phenotypic information need to be designed and incorporated into complete models and algorithms. While kept separately it is evident that this gap and the one treated in the following box overlap. Indeed the issue of interpretation and modelling through algorithms is discussed under the next gap. The same applies for the issue of how to use data gathered under “**uncontrolled conditions**” also discussed under the next gap.

Box 2 Auto-adaptive algorithms (# 47 of Full List)

Need of auto-adaptive algorithms autonomously adjusting clinical parameters to individuals' conditions	
Rationale	<p>Extended amount of data is collected, however its transformation to valuable knowledge in terms of what the data means, is limited => requiring continuous intervention of healthcare professionals and confining PHS only to monitoring with little actuation and treatment.</p> <p>In combination with clinical evidence and bio-medical and genetic information, need of interpretation of body signals in the perspective of "body and mind" and of contextual conditions;</p> <p>Overcome current standardisation in clinical parameters => automatically adapt to individuals' conditions and produce real personalisation of PHS</p>
Research items	<ul style="list-style-type: none"> • Improve data fusion and integration of data coming from different sources; • Improve self-adaptivity and self-calibration of algorithms to enable personalised data processing, which means recursively taking into account, and learning from, individuals' unique contextual (environmental and emotional) and genetic characteristics together with vital and physiological signs; • Devise correction/rectification techniques to normalised data gathered under "uncontrolled conditions"
Overlaps/complementarities	<ul style="list-style-type: none"> • With box 1 (processing and interpretation of clinical evidence and bio-medical and genetic information) • With Boxes 4, 7, 14 on sensors (context awareness and multi-signs/multimodality) • With Boxes 3, 5, 13 (instrumental to prediction and modelling)
Other	<ul style="list-style-type: none"> • Controlled studies to correlate and compare data obtained in both "clinical settings" and "uncontrolled conditions" to identify normal and abnormal patterns taking into account personal and contextual factors (to be use for correction/rectification) • Full inter-operability among different PHS devices and between them and Personal Health Records (PHRs)

Gap description

Already at the end of our work on the State of Play and before the all consultation process started we concluded that *PHS today are called 'personal' as the focus is on the person possibly outside of institutional care but they are not necessarily personalized.* Currently, PHS data analysis focuses on standard measures, commonly accepted in medicine, to detect abnormal physiological conditions or, in the case of aging, abnormal physical state (i.e., early fall detection), without considering context (environmental conditions, location, type of interaction i.e. from voice signalling, emotional state) and person specific parameters (age, social class, education, life history, genetic characteristics). PHS applications still concern a limited number of parameters that can vary within a pre-defined range, without the capabilities to take into account peculiar conditions and characteristics of the individual, and to automatically adapt the expected values of medical parameters. This can lead to false positive early warning: that is a vital signs is above the threshold but this may be due to peculiar characteristics of the individual or of the specific context in which he/she is. In this context healthcare

professional intervention is still a major part of current PHS solutions. A corollary of which is that actuation and treatment through PHS is still far away, while monitoring remains the main focus of today's personal health systems. In case of acute episodes, today's PHS is too limited in terms of automatic and in-time intervention. To become truly *personalised*, requiring less intervention on the side of healthcare professionals and enabling more actuation and treatment, PHS must be powered by *auto-adaptive and self-calibrating data processing and interpretation/modelling solutions*, on which to build systems that do not only monitor the condition of an individual, but also deliver on-time and evidence-based prediction supporting actuation.

Gap Storyline

Filling the previous gap by integrating clinical and biomedical/genetic information into PHS, would be insufficient without: a) the capacity to process all the relevant data and extract from it reliable knowledge and prediction; and b) to recursively self-adapt and self-calibrate the data processing in view of the patterns uniquely specific to each individual and of the changing context (environmental and emotional factors). Assuming we can have information on all needed parameters (vital-, physio-, gene-, emotional- and environmental- factors), the level of intelligence within the PHS data processing sub-system must increase and incorporate complex algorithms capable of both knowledge extraction and of self-adaptability and self-calibration. If this is achieved, then PHS applications not only benefit from existing knowledge but would further contribute to its advancement: for each individual and/ or groups of individuals patterns may be identified. Further, as a statistical basis is built, negative episodes are possible to be detected in time, and consequently, it is possible to act upon them.

A particularly important dimension is the fact that, in most cases the data produced by PHS, if we compare them to those from traditional clinical settings, will originate within what can be deemed “**uncontrolled conditions**”. This means that the value of the parameters gathered may be influenced by situation specific environmental and/or emotional factors. Data thus produced can be interesting to clinicians but currently cannot be used, for instance, to take decision on treatment. Risk thresholds for certain parameters (based on statistically observed patterns in clinical settings) shape decision making about treatment in medicine. The data produced from PHS cannot be used against those risk parameters as long as they originate in “uncontrolled conditions” that may cause measurement errors (leading either to unnecessary intervention or to not intervening when needed). This has two implications. First, controlled studies are needed including measurements on a number of parameters for a given sample of individuals in both clinical settings and in “uncontrolled conditions” as to include personal conditions and environmental factors. These should enable to assess normal and abnormal patterns in light of personal patterns and context. Second, with this input PHS powered by innovative self-adaptive algorithms should recursively process data and identify truly abnormal patterns, as well as rectify/correct parameters that may appear as abnormal only due to very peculiar contextual conditions.

Evidently this gap cannot be seen in isolation, in other words achieving the potential outcomes of personalised PHS enabling actuation does not depend only on filling it up. First, the earlier seen integration into PHS of clinical evidence and of bio-medical and genetic information must also be accomplished. Second, advancements in sensors, which are treated later, are also needed. Currently sensors capturing contextual parameters and

other individualised data beyond vital and physiological signs in a reliable way are lacking. Third, a sub-component of this gap related specifically to environmental factors and body motions and gestures is further discussed in details as a separate gap (see Box 4). Last and certainly not least, important advancements are needed in terms of interoperability since different PHS devices will need to communicate among each other and to read from, and write onto, Personal Health Records (PHRs). Yet, if all of this will occur, it will be *sophisticated algorithms and data processing solutions that must turn inert data and information into knowledge and knowledge into wisdom (which knowledge for which action)*, thus, laying down the ‘last mile’ toward reaching the vision behind PHS.

Box 3 Clinical guidelines and pathways (# 26 of Full List)

Need of PHS systems holistically embedding clinical guidelines and pathways	
Rationale	<p>There is need for software systems coordinating the activities of all health professionals involved in the treatment of a patient, aligning care delivery around best practice guidelines</p> <p>In brief: Guidelines are mono-focused on single health conditions (i.e. one guideline per disease) => Need of guidelines enabling simultaneous assessment of several statuses, and hence their effect on each other.</p>
Research items	<p>Integration and modelling into PHS of “holistic” clinical guidelines that:</p> <ul style="list-style-type: none"> • Address co-morbidities; • Consider emotional, behavioural personalised factors • Capture chrono-biological and environmental aspects
Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 1 and Box 2 (integration and interpretation of clinical evidence and bio-medical and genetic information, including issue related to data gathered under “uncontrolled conditions”) • Boxes 2,4,7 (On context awareness); • Boxes 5 and 13 (on prediction/modelling)
Other	<p>Need of more cooperation between different professional profiles in different tiers of healthcare, and between them and research</p>

Gap description

The “Self-Caring Society” scenarios also elicited this gap calling for the need of PHS to embed holistic clinical guidelines and pathways to: a) ensure appropriate use of PHS; b) guide healthcare professionals. The gap emerged also with regard to the rise in chronic-diseases co-morbidities requiring an integrated approach across domain of specialisations and tiers of the healthcare. There is still need for software systems coordinating the activities of all health professionals involved in the treatment of a patient, thus aligning care delivery with best practice guidelines and these systems should inform PHS applications.

Gap Storyline

Clinical guidelines are a crucial component of any diagnosis and/ or treatment. However, current guidelines are designed vertically, i.e. they do not take into consideration cross-dependencies of other diseases (co-morbidities) nor do they take into account how behavioural, contextual and environmental aspects affect a certain clinical condition. In order to achieve closed-loop systems, it is of major importance to develop more complete guidelines taking into consideration cross-dependencies and effects of several conditions

and states. Additionally, it is also important that clinical guidelines are continuously updated according to new releases and achievements in the field. Accordingly, and in combination with other external information (i.e. trials, bio-banks etc), it is possible to achieve (by applying risk profiling) a well defined risk stratification, which in turn enables PHS to be tailored to patients’ needs, preferences and what is considered to be “individual normal status” instead of applying “general guidelines”. Evidently filling this gaps in not only a matter of technology and research, but it also required more collaboration across different tiers of the healthcare system and also with research (in this respect see gaps 3,4,5 of **Full List** that relate to implementation issues)

Box 4 Monitoring techniques linking various parameters (# 49 of Full List)

Lack of monitoring techniques able to correctly link physiological signs and motions, gestures, and environmental data	
Rationale	Go beyond vital signs => integration of contextual, emotional posture and gestures data Multi dimensional data monitoring and processing => comprehensive representation of patients’ status, encompassing all aspects (physical, contextual and psychological)
Research items	<ul style="list-style-type: none"> • Context awareness, multi signs and multi-sensors data integration (see later Boxes 7 and 14)
Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 2 (Advancements in data processing)
Other	<ul style="list-style-type: none"> • Incorporation of developments in human-computer interfaces (in order to “read” emotions though facial expressions and gestures, see later) and ambient intelligence

Gap description

PHS applications do not combine “external” signs (e.g., from external environment such as sound, light, particles, etc; from the patients’ body, like gestures and motions) with vital signs, to better tailor medical treatment and monitor patients’ conditions according to his/ her context.

Gap Storyline

Current PHS applications gather and process data detected on patients’ body, without taking into account the context in which patients are, such as environmental conditions (light, sound, particles in the air), and context (e.g., patients are at home, outside, training, etc.). In addition, these applications do not include sensors for human gestures and facial expressions that, duly interpreted and processed, help in understanding their emotional and psychological situation. This situation reduces the understanding of patients’ real conditions (like, for instance, their emotional and psychological conditions, or some particular environmental risks they are exposed).

Linking all these aspects (and the corresponding data) is a key feature for better understanding patients’ reactions to treatment, and avoiding “false positives”, when, for instance, patients overcome some limit parameters because they are training. In the same way, these applications favour continuous monitoring, as well as a more accurate risk stratification in the measure of PHS exchange information with PHRs and epidemiological databases.

Developing these techniques encompasses several aspects, including: understanding what measures are relevant (to reduce redundancies), how they are interrelated, which are the best sensors to gather such information, optimising data processing.

Box 5 DSS for healthcare professionals (# 27 of Full List)

Need of innovative and holistic DSS for healthcare professionals based on prediction/simulation/visualisation	
Rationale	<p>Current PHS is limited to monitoring mostly vital and physiological signs. Need to consider the complexity of the human body including also contextual and emotional parameters</p> <p>Go beyond vital signs => comprehensive picture of human body to support decision through prediction/modelling and simulation/visualisation</p>
Research items	<ul style="list-style-type: none"> • Develop new predictive, modelling and visualisation/simulation capacities for PHS (connected with deeper understanding of links between genotype and phenotype, that is integration and combined processing of several different sources of data)
Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 1 and Box 2 (integration and interpretation of clinical evidence and bio-medical and genetic information) • Box 2 (data processing) • Box 6 (visualisation) • Box 13 (modelling and prediction)
Other	<ul style="list-style-type: none"> • Virtual Physiological Human (VPH) developments

Gap description

Again the “Self-Caring Society” scenario with empowered users demanding symmetric interaction with healthcare professionals was the source of discussion around the need for innovative Decision Support Systems based on predictions, simulation, and visualisation. It then also emerged that such tools, although mainly conceived for healthcare professionals, could also become a DSS shared between users and professionals.

As for other issues considered, also these tools should go beyond vital and physiological signs and consider the complexity of the human body including also contextual and emotional parameters.

Gap Storyline

In this context PHS, besides advancement in traditional data processing, could benefit from integration of advancement reached by Virtual Physiologically Human (VPH). As VPH models are both descriptive, predictive and additionally formed taking into consideration pathological, physiological, and anatomical data, they can become the basis for a PHS new DSS primarily for clinicians but eventually possible to share with users. VPH is further important for developing interfacing technologies that give a just picture of personal aspects, both for clinical use, and for patients to give an illustrative picture of how each individual body is formed and affected by different actions and behaviours. In addition there is also a contribution from PHS to VPH that could derive from this integration. Convergence between PHS and VPH further means that PHS provides better measurement and reliable data so that VPH build better models with in turn produce better design of artificial organs to be implanted and become also part of PHS

Finally, thinking very futuristically, there could be spin-offs from such integration between PHS and VPH, positively over spilling on the users. It could produce a sort of “tamagochi” of oneself, a device that can tell everyday how one has performed, and whether or not one has behaved well towards his/her health. This could be among those tools that could motivate people to behave in sound and preventive fashion (if they are healthy), to refrain from certain specific behaviours (if they have been diagnosed with a potential future risk), to adhere to prescriptions and lifestyle guidelines (if they are already chronic patients and/or are following a rehabilitation programme).

Box 6 Imaging and visualisation (# 43 of Full List)

Need of imaging and visualisation techniques for intuitive and easy to interpret input	
Rationale	PHS solutions are limited in interaction and transmission of information in a perceptive manner=> Development of intuitive and easy to understand tools
Research items	Incorporation of self- and environment imaging (integrated with audio and sensing techniques)
Overlaps/complementarities	<ul style="list-style-type: none"> • Box 5 and Box 13 (for what concern visualisation)
Enablers	<ul style="list-style-type: none"> • Ambient Interfacing • Ambient Intelligence and Intelligent Mixed Reality • Immersive Virtual Tele-presence

Gap description

Current PHS applications do not include imaging and visualisation functionalities, which could help citizens and patients in better understanding their health conditions, by visualising them.

Gap Storyline

Citizens’ and patients’ awareness about their health conditions and understanding of the ongoing of the therapies are key issues, both for ensuring compliance and for optimising treatment.

Through imaging and interfacing techniques, patients and citizens may be further equipped in digital environments that is not limited to their physiological status, but also to their presence and context. Consequently, and by taking advantage of the latest developments in enabling technologies, PHS solutions should be designed in a perceptive, adaptive, and most importantly reactive way.

The importance of interfacing becomes especially apparent in the case of cognitive and physically declined groups; e.g. the elderly population. Hence, it is of major importance to design PHS solutions that are able to transmit proper information and knowledge to users in the most optimal and natural way.

Images can be extremely communicative, and more persuasive than any medical suggestion of clinical guideline. Thereof, imaging and visualisation features included in PHS can ensure an immediate and effective communication to citizens and/or patients, facilitating the use of these devices, and enhancing compliance at the same time.

Box 7 Sensors for context awareness (# 48 of Full List)

Need of sensors monitoring different kinds of signs ensuring context awareness	
Rationale	Go beyond physiological signs => collection of contextual data Achieve real continuous monitoring => data gathering in uncontrolled environment
Research items	<ul style="list-style-type: none"> • New sensors capturing context (environment, emotional status, punctual location and situation, etc); • Optimisation of on-board processing capability • Integration of data from “external” sensors (i.e., sensors not on patient’s body)
Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 1 and Box 2 (issue of data from “uncontrolled conditions”) • Box 2 and Box 14 (multiple signs and multimodality) • Box 8 and Box 14 (Optimisation of sensors architecture)
Other	<ul style="list-style-type: none"> • Human-computer interaction / affecting computing

Gap description

As anticipated under Box 2 on auto-adaptive and self-calibrating data processing as a key pillar toward personalisation, such processing can be improved only inasmuch as data are gathered by sensors on parameters going beyond vital and physiological signs. In this respect there is a need to develop sensors capturing context, emotional, and more in general punctual conditions of individuals.

Gap Storyline

Contextual data to be integrated into PHS applications could be of different nature: from simple time and location, to environmental physical and chemical conditions (like particles in the air, light conditions, etc). Furthermore, individuals’ geographical position posture and movements should be monitored, detecting alarm situations (in case of fall, for instance), abnormal behaviours (like sleep disorders), or even simple stress situations. Emotional parameters should be able to detect from facial expressions, posture, gait, speech, etc. psychological status of individuals, which can influence individuals’ health parameters. While some of this information are available (GPS functionalities, proving time and location information, are a common feature of mobile phones), others require integration of new sensors.

Combining these signals with physiological ones would allow to finally having a more comprehensive picture of individuals’ real conditions, enabling to correctly link changes in physiological parameters with environmental and psychological factors. Advancements in this area would also allow contribute to fill the gap of data gathering in uncontrolled environments, discussed earlier under auto-adaptive and self-calibrating algorithms.

It is probably pleonastic to add that, by definitions, sensors capturing these parameters outside of individuals’ home would need to include on board processing and wireless capacities to transmit the results of data processing. Finally, the monitoring systems should be able to collect /receive information from external sensors, which are neither on the individual’s body nor in his/her home. For instance, public systems monitoring the status of air in a city may be captured by sensors that are not on the individual’s body.

Box 8 Low adaptability of PHS to individual characteristics (# 54, 36, and 45 of Full List)

Low possibility to adapt PHS components to individual characteristics	
Rationale	Go beyond current standardised PHS architecture => “plug and play” components, to be combined on the basis of individuals’ needs. Overcome fixed design => “modular” architecture, better adapting to individuals’ characteristics and changes over time. Addressing also the issue of non invasiveness and of possible allergies to, effects of, sensors depending on individuals’ characteristics.
Research items	<ul style="list-style-type: none"> • New sensors’ materials (e.g., biological and molecular sensors); • Integration of alternative energy supplies, e.g. body energy • Optimisation of PHS sensors’ networks architecture and components (modularisation, plug & play) • Self-calibration of sensors
Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 2 (self-calibration) • Box 7 (architecture) • Box 14 (architecture and self-calibration) • On sensors materials: Boxes 9, 15, 16, 17
Other	<ul style="list-style-type: none"> • Design of innovative and open body area networks; • Standardisation of PHS components’ inter-communication protocols and advancements in interoperability • MEMS and NEMS

Gap description

Current PHS applications are developed with a pre-defined architecture (also in terms of components, including sensors) that do not allow to take into considerations patients’ peculiar needs (like, for instance, type of daily activities and related needs in terms of freedom of movement and comfort).

Gap Storyline

A truly personalised PHS application has to be as comfortable as possible, becoming “invisible” in users everyday life. This entails optimisation of PHS “hardware” components (especially those, like sensors, positioned on patient’s body), as well as a sort of “modular” composition of PHS applications, in order to better adapt to individuals’ needs and characteristics. So far, PHS applications have had a quite well-predefined composition, in order to optimise data gathering and processing. Many components have been developed ad hoc for each applications, with very low or no possibility to modify the architecture and the components after the design phase. The full realisation of this PHS feature implies, among others, the possibility to adopt sensors made of different materials (because of patients’ allergic reactions to certain elements, for instance), as well as the customisation of sensors positioning, in order not to reduce patients’ freedom of movements and maximise their comfort. In addition, it has to be possible to add home components (like cameras for posture and fall detection), in case of need (for instance, after acute events, or beginning of neuro-degenerative diseases). In this sense one can envisage sensors networks designed starting from individuals’ specificities, in terms of mobility requirements, disease or diseases suffered, sensors materials, type of treatment needed, etc. In this ways, all the components of the sensors networks could be perfectly tailored, and eventually modified according to changes in users’ requirements (like, for instance, reduced mobility, new diseases, etc.). The possibility of a modular sensors

network architecture would change the current paradigm of PHS, under which sensors and sensors networks are developed for the application, and users have to comply with the systems requirements. On the contrary, in this way, the application is developed for the users, and can be adapted over time. This research would dramatically increase to potential for PHS adoption, filling the gaps concerning lack of multi-disease application (while the number of people suffering from co-morbidities constantly increasing), and lack of tailoring (this applies also to gap summarised in Box 14). Naturally, if network of sensors have be adaptable this mean that they must also be reconfigurable in run-time, in the sense of adapting their operational logic to specific situation. This calls for the additional challenge of developing self-calibrating sensors. Evidently if we are talking about a sensor with on-board processing, then the issue of self-calibration is practically the same as that of auto-adaptive and self-calibrating algorithms discussed in box 2 for the data processing system. This is so because with on-board processing the conceptual distinction between the data processing sub-system and the sensor components cease to be relevant.

Box 9 Sensors long term effects (# 25 of Full List)

Lack of data on long-term effects of contact between human body and sensors	
Rationale	Effects of radio waves and long term contact with body of PHS not known => Use of “safe” devices and materials.
Research items	Incorporation of alternative organic and/or molecular sensors.
Overlaps/ complementarities	<ul style="list-style-type: none"> • On sensors materials: Boxes 9, 15, 16, 17
Other	<ul style="list-style-type: none"> • Controlled clinical investigation of long term effects of sensors; • Development of alternative micro/ nano sensors in organic and/ or molecular material

Gap description

The two scenarios on the “Self-Caring Society” and the “Caring State” foresee a wide deployment and usage of PHS. This has led several experts to raise the issue of the long term effect of continuous contact between the body and sensors, in addition to radio waves.

Gap Storyline

There is still little evidence on the links between long term usage of body connected sensors and risks of developing certain conditions, as e.g. allergies or for developing cancer. Nevertheless, there are many upcoming and promising micro- and nanotechnologies that develop sensors from organic and molecular material, which may limit the negative effects. However, more clinical investigation is needed to verify their limitation of negative effect and exposure. This very important as a guarantee against the possible side effects that may derive from filling the gaps discussed in Box 15 (actuators), Box 16 (personalised drug delivery), and Box 17 (endoscope capsules).

Box 10 PHS embedded eLearning (# 42 of Full List)

Need of PHS embedded eLearning	
Rationale	PHS solutions do not incorporate knowledge transmission and hence, prevention is not sufficiently highlighted => Develop solutions enabling users to be co-producers of health
Research items	Incorporation of easy to use training modules into PHS applications

Gap description

There is need for eLearning included in PHS application, which provides users with medical reliable specific training on their health conditions and treatment, and in a more general way on related issues.

Gap Storyline

Raising awareness and increasing users’ knowledge about lifestyle management and on disease-related issue are considered as crucial aspects in prevention and patient management. So far, PHS applications only provide some guidelines and suggestions concerning dietary habits (mainly on the basis of RFID technology). eLearning applications need to be developed in cooperation with all the span of “medical” personnel, from personal trainer to the pathology specialist, ensuring scientific control and thus reliability of the information provided. However, they need to be easy to understand (even to a non medically educated audience) and to note therefore, interactivity and user friendliness have to be included in development. Incorporating eLearning into PHS would lead to an increase of users’ awareness and knowledge about their health conditions, and to a deeper understanding of therapies and treatments undergoing. This condition could also reduce resistance, concurring thus to increase compliance towards medical therapies and lifestyle management suggestions, reducing thus the incidence of acute situations, by also taking into consideration motivational aspects.

Box 11 Solutions for multi-channel interaction (# 41 and 44 of Full List)

Need of new technological solutions enhancing development and implementation of multi-channel interaction systems	
Rationale	Lack of diversity in PHS tools => enhance mobility and multi-modal interaction possibilities.
Research items	<ul style="list-style-type: none"> • PHS applications delivered through many channels at the same time; including: Digital TV; Web (including social networks); Mobile communication devices; • Enhancement of human-computer interaction in PHS
Overlaps/ complementarities	<ul style="list-style-type: none"> • Human-computer interfaces, affective computing (Boxes 7)
Other	<ul style="list-style-type: none"> • Human-computer interaction, affective computing • Mobile and broadcasting communications.

Gap description

In current PHS applications, there is still lack of multi-channel delivery of the service, as the device used for communication (both from and to the patient) is only one, in most cases a PDA or a smart phone.

Gap Storyline

Confidence towards technology and devices differs among different groups of users and even single users, as well as their mobility patterns do. Multi-channel delivery of services, through PHS applications, can be developed in order to reach different segments of potential users (e.g., young people, elderly, chronically sick patients at home, etc.) in the most convenient way. Delivery channels for the same application can be combined on

the basis of citizens/patients needs on terms of user-friendliness, type of connection required, etc., leading to two-way interactions similar to face2face interactions.

Box 12 Quality controlled web 2.0 (# 52 of Full List)

Need of quality controlled web 2.0 tools	
Rationale	Avoid current contradictions and inconsistencies in available health information => scientific control of health information on the Web Better exploit participatory network potential => incorporate such functionalities into PHS
Research items	Integration of Web 2.0 applications into PHS Criteria for scientific control and supervision of participatory Web 2.0 tools
Other	Incorporation of advancements in Web ontologies applications

Gap description

Participative Web 2.0 tools active in the medical field are many today, but lack of scientific and medical control, and integration in PHS applications.

Gap Storyline

In order to have a third opinion, or to gather more information about health conditions and treatments more in general, an increasing number of people rely on the Web. Web 2.0 tools providing medical information and patients' experiences (like Forums and participative websites) are increasing in number and daily accesses. However, there is no control of the reliability of medical information provided. Including Web 2.0 tools into PHS applications entails supporting and assisting a participative network of users, which can provide support to each other, increasing compliance to treatment and effectiveness of care. This implies also guaranteeing scientific and medical reliability of the information provided. In this way, Web 2.0 tools incorporated into PHS applications can make it easier to find reliable information about a certain disease or drug, for instance, reducing the risk of misbehaviour due to wrong information. Clearly, these tools have to be easy to use, with intuitive surfing through different topics and subjects.

Box 13 Patient decisions aid tools (# 51 of Full List)

Need of intuitive patient decision aid tools	
Rationale	Provide support to patients' decisions and treatment => integration of users' friendly prediction and simulation tools Provide support to patients' decisions and treatment => incorporation of motivation sustain and psychological support
Research items	<ul style="list-style-type: none"> • Integration of simulation tools based on prediction and modelling • Integration of user-friendly interfaces and visualisation techniques
Overlaps/complementarities	<ul style="list-style-type: none"> • Data processing of several sources of information, prediction, modelling, visualisation/simulation (Boxes 1, 2, 5, • Holistic guidelines (Box 3) • Human-computer interfaces, affective computing (Boxes 7 and 11)

Gap description

In order to have effect, changes in lifestyle and medical treatment need involvement and commitment by citizens and patients, who can be helped with the incorporation of prediction and simulation tools and motivation support into PHS.

Gap Storyline

When in need of treatment, and/or of changes in lifestyle, patients and citizens want to understand the reasons why certain decisions are taken by the medical personnel. This is particularly relevant for the most educated parts of the target, that are willing to know the different options (while available), and the different perspectives they imply (in terms of conditions in few years, long-term effects, etc.). Patients aid tools with prediction and simulation capabilities can lead to an increase in patients' and citizens' awareness and knowledge about their health conditions. More educated and aware patients and citizens can thus better negotiate with doctors their therapies and treatments, when being able to see and understand short-and long-term effects of their treatment and behaviour. In the same way, when undergoing a change in lifestyle (like stopping to smoke, for instance), or starting a treatment, citizens and patients need psychological support, in order to comply with medical prescription and/or modifying their behaviour. Current developments in PHS do not provide features that help in supporting patients and citizens with regards to these aspects. Incorporation of patient decision aid tools requires the development of models that help to project patients' conditions in the future (with a limited time-horizon), predicting their conditions. In additions, visualisation and interfaces techniques that allow PHS final users to easily understand and interpret the results of the prediction and simulation exercise. In addition, motivation support has to be provided in a personalised and tailored way. This feature encompasses incorporating behavioural and psychological pathways into PHS, as well as personal motivation techniques.

Box 14 Multi-signs/ multi-disease sensors (# 7 and 13 of Full List)

Lack of multi-signs/multi-disease sensors	
Rationale	Avoid current fragmentation => integration of data acquisition in one single unit, thus reducing the number of components (and related data transfer activities) and the corresponding energy consumption (and waste) and bandwidth needs Go beyond vital signs => collection also of contextual and emotional data. Overcome disease-specificity in design=> adaptable and standardised plug-and-play systems (common rationale with gap of Box 8)
Research items	Optimisation of multimodality to ensure multi-disease and multi-signal assessments;
Overlaps/ complementarities	• Box 8: optimisation of sensors architecture and self calibration of sensors and self-calibration of sensors
Other	• MEMS and NEMS

Gap description

As we documented in the state of play, currently in the majority of applications we have 1 sensor per sign and per disease, which means that for monitoring only one disease we need several sensors. Adding that on-board processing within sensors is very limited, if we tried to increase the coverage of diseases and of the signs monitored to achieve personalisation (i.e. context awareness and individuals' unique characteristics) using currently available solutions we would have to use a large number of sensors and we would need to transfer a lot of data. This amounts to an inefficient use of bandwidth and energy. The insufficient integration of sub-systems results into high bandwidth

requirements and power consumption (data gathering and processing separated, -> large amount of data to be inter-communicated). In addition to inefficient use of resources, the way of obtaining, analyzing and communicating data is still too complex, using too many channels and being scattered across too large geographical areas.

Gap storyline

First, this problem could be avoided by introducing sensors capable of monitoring multi-signs and multi-disease exploiting diversity in sensing modalities to provide accurate and rich information about the target. Second, increasing sensors on board processing would also decrease the demand on energy and bandwidth. A more encompassing way to look at the issue is from the perspective of sensors networks (see considerations following gap described in Box 8).

Box 15 Actuators (# 2 and 46 of Full List)

Lack of actuators	
Rationale	Limit professionals' intervention => closed-loop solutions encompassing diagnosis (<i>endoscope</i>), dispensation, reaction and monitoring
Research items	All-encompassing sensors/actuators, incorporating several functions (like sensor, actuators and communication) using new materials and reducing invasiveness;
Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 8 and Box 9 (sensors materials and invasiveness)
Other	<ul style="list-style-type: none"> • Development of alternative micro/ nano sensors in organic and/ or molecular material • MEMS and NEMS

Gap description

Health status monitoring is the main focus of available PHS applications, lacking closed-loop systems able to directly “acting” on individuals’ conditions and monitoring results.

Gap Storyline

Truly personalised PHS need to integrate several functions into one application, including assisting in diagnosis *and* treatment (treatment is not limited to medication but include nutritional and behavioural aspects). This term should, however, not be limited to injection of medication, but also include provision of feedback when results are obtained or failed, thus including (in-time) alarm functions. This would lead to true closed-loop systems that empower citizens to take charge of their own condition, and consequently, limiting professionals’ intervention to a minimum.

Box 16 Personalised drugs delivery (# 34 and 35 of Full List)

Need of sensors for personalised drug delivery and compliance	
Rationale	Enhance compliance to medical prescriptions => personalised reminders functionalities Detection of drug intake/conformity to prescription => patients' continuous monitoring and alarms functionalities Reducing care burden => automatic drug delivery
Research items	<ul style="list-style-type: none"> • User adaptive reminders (active both at home and outside) • Integration of implantable minimally invasive drug delivery systems

Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 8 and Box 9 (sensors materials and invasiveness)
Other	<ul style="list-style-type: none"> • Development of alternative micro/ nano sensors in organic and/ or molecular material • MEMS and NEMS

Gap description

Adherence to medical and lifestyle prescription is quite low, due to poor reminders functions and automatic drug delivery systems.

Gap Storyline

Poor adherence to medical prescriptions and lifestyle guidance is a major challenge facing health care. Low compliance can be due to several factors, including forgetfulness, complexity of the regimen, disruption of daily routines, and, in some cases, intentional experimentation. Of these, forgetfulness and complexity of the regimen (many patients, especially chronic, have to take several medications many times during the day, with different timing) can be considered as the most relevant. Moreover, errors in following the regimes (i.e., taking the medication at a wrong time) are quite common. Current applications include reminder functionalities, which however, are insufficient to ensure real compliance (it is not possible to check if the patient actually did what he/she was reminded to). PHS applications need to incorporate advanced reminder functionalities, able to detect the effective drug intake in the time window foreseen and/or medicament application, monitoring their effects on patients' bodies. In addition, implantable devices, encompassing drug delivery functionalities, besides monitoring, can be developed, in order to provide patients with the right dosage of the right medicine at the right time.

Box 17 Endoscope capsules (new gap)

Endoscopy capsules	
Rationale	<p>Reducing invasiveness of certain medical exams => smart pills for endoscope to be swallowed or injected.</p> <p>Enlarge PHS diagnosis capability => integration of endoscope capsules in PHS applications</p>
Research items	<ul style="list-style-type: none"> • Development of automatic orientation and navigation systems; • Integration of medical imaging techniques; • Incorporation of easy to use interfaces.
Overlaps/ complementarities	<ul style="list-style-type: none"> • Box 8 and Box 9 (sensors materials and invasiveness)
Other	<ul style="list-style-type: none"> • Advancements in research in very small/alternative energy supply systems; • Development of alternative micro/ nano sensors in organic and/ or molecular material • MEMS and NEMS

Gap description

“Smart pills” can be integrated into PHS applications, in order to avoid medical intervention for endoscopic exams.

Gap Storyline

Many patients need to undergo diagnostic and/or periodic endoscopic control exams. Until now, they need to recur to a medical structure (usually a hospital) in order to have such tests. PHS applications can integrate (when the case is needed) robotics applications like “smart pills” enabling endoscope functionalities. In this way, patients can avoid invasive medical exams, and results can be directly visualised and integrated into PHS applications, reducing time to results and request for medical supervision when needed.

Box 18 Biomarkers per Lab-On-Chip (# 8 of Full List)

Encompassing Biomarkers per Lab-On-Chip are limited to 2-3	
Rationale	Avoid fragmentation of testing, i.e. use of traditional lab tests to complete POC testing => encompassing the all biomarkers needed to run a complete assessment into one single biochip
Research items	Investigation on including more than a few biomarkers onto one single lab-on-chip; Further inclusion of genetic info testing
Other	<ul style="list-style-type: none"> • Research results on “new” biomarkers more adapted to POC • Integration of Micro-Opto-Electro-Mechanical-System (MOEMS)

Gap description

Current Point-of-Care systems can run tests (blood, urine etc) limited to 2-3 biomarkers. This often leads to that physicians run completing tests through traditional means (i.e. laboratories), due to that they need to base their diagnosis on several factors that are inter-independent.

Gap Storyline

Medicine is a multi-factorial principle, which means that you never do a diagnosis based only on one factor; it is a combination of factors that lead to a diagnosis. Point-of-care diagnosis was developed with the idea of rapid testing avoiding to wait for time-consuming results. However, since the current tests that are available today run in most cases only 2-3 biomarkers, they lead only to incomplete diagnosis i.e. they show only a tendency towards a certain disease or a certain condition. Some types of “easy” tests, such as pregnancy, certain types of infections etc can still be run through these applications. However, and specifically for screening for more acute diseases, more biomarkers are needed to achieve a full-scale diagnosis. Hence, it is of major importance to encompass all additional biomarkers needed for a complete diagnosis in one single lab-on-chip. Further on, as point-of-care holds potential also for tests requiring genetic information, it becomes more evident that many more “markers” are required to be included. As known, any DNA sequence is build-up by a multitude of crucial parts that all lead to a part of a result, as e.g. testing for auto-immune diseases.

Box 19 PoC sample preparation (# 9 of Full List)

PoC sample handling and preparation still, in most cases, requiring human intervention	
Rationale	Limitation of human intervention and consequently, adverse errors and long lead time => Human intervention to be limited to only applying sample onto the lab-on-chip.
Research items	Development of automatic and on-board sample preparation; Examination on automatic calibration.
Other	<ul style="list-style-type: none"> Further research on micro-fluidic techniques optimising sample course control.

Gap description

In most cases, and after extracting a sample from a patient, there is still a need for professionals to, one way or another, prepare the sample. This includes often several steps, before actually applying the sample onto the lab-on-chip for final analysis.

Gap Storyline

The fundamental basis of any test is that the samples hold the desired quality. Body fluids (which are the kind of samples mostly used in these occasions) are very sensitive to environmental factors, e.g. temperature and contamination. Thus, it is risky to have a several-step intervention before running the test. How can the quality of the sample still be assured? And most importantly, how can the results be guaranteed in terms of accuracy? If the basis is un-stable, does it not also lead to too many false-positive results? And if it does lead to false-positive results, will it not lead to wrong diagnosis?

As can be understood, there are too many questions left un-answered. Hence, it leads to too many risk factors, which in turn can lead to un-avoidable increased cost and workload. Thus, the steps from sample extraction to sample application onto the chip have to be decreased to a minimum, in order to assure a valuable quality of obtained results.

Box 20 PoC time to result too long (# 10 of Full List)

PoC time to result is still too long	
Rationale	Sample analysis results are obtained with drawn out waiting time => optimise time to result
Research items	Optimising of fluidic control and run-time
Other	<ul style="list-style-type: none"> Further research on alternative array technologies adapted to POC-solutions

Gap description

Current POC solutions require a minimum of 15 minutes of run-time and time to result. In most cases, this does not even include the time of sample extraction and sample preparation. Including those steps often lead to additional waiting time, up to several hours.

Gap Storyline

When a physician receives a patient, he/ she are bound by at least one important factor in order to diagnose and/ or monitor a condition; time. This time, in most European countries, is limited to 15 minute, in some easier conditions; it is even reduced to 5

minutes. POC is designed to be a decision aid tool to professionals in order to take more in-time and accurate decisions. However, current systems are still too complex and too time-consuming, that both physician and patient are subject to unnecessary waiting. This further means that the optimisation of healthcare workflow is still not fully achieved. Consequently, in order to accomplish a closed loop circle of testing and diagnoses, the time needs to be drastically reduced.

4.3 Organising the gaps: from storylines to research domains

The synthetic boxes and the supporting gaps descriptions and storylines illustrated in the previous paragraph reflect the discussions and input of the consultation process. It is evident, however, that they are in need of being further conceptually re-organised and re-elaborated to serve as the platform for the final consultation events on roadmapping. In the course of illustrating them we already provided hints at overlaps and complementarities between the research themes preliminarily associated to gaps. This re-conceptualisation was accomplished during the 5th meeting of the ESC and benefited from the insights and expertise of the experts, whose final output is summarised in Table 5 presented in next two pages and commented in the rest of this paragraph. This table to some extent selectively and freely re-use and re-phrase the contents of the gap boxes and storylines presented in the previous paragraph in light of the considerations that follow. For the sake of clarity, however, the numbers of the related gaps' boxes are also reported at the bottom of each group, in order to reduce the possible confusion generated by the necessary rephrasing.

There are two lenses through which we can re-compact and understand in a coherent picture those that could at first sight appear as disparate and disjoint gaps.

First, the gaps of the **Short List** are *connected by the thread of making Personal Health Systems truly personalised and efficient, which means that they function:* a) capturing the very peculiar characteristics of individuals (vital and physiological signs, but also their genetic outlook, as well as their clinical history, and their socio-demographic and socio-economic conditions); b) ensuring awareness of very punctual contextual conditions (location, activity being performed, emotional status, physical and chemical conditions in the environment, etc); c) intelligently processing such information to support traditional action and automatic actuation, thus, bringing new applications and services going beyond monitoring; d) using devices as minimally invasive and comfortable as possible adaptable to the very personal specificities and needs of each single individuals (i.e. avoiding materials to which one may be allergic, or which may negatively interact with individual specific health and contextual parameters, or which may have negative long term effect regardless in general) ; e) providing 'front-end' fruition modalities that respond to different attitudes and needs of different typology of users;

Second, most of them have been elicited mainly by the two most relevant scenarios from the perspective of PHS: *the "Self-Caring Society" and the "Caring State"*. These two scenarios elicited gaps and research themes that would either support their desirable elements or offset their undesirable ones. Both of these two scenarios, although for different reasons, envisage the large scale deployment and usage of PHS in the future. In the "Self-Caring Society" health consumerist and technology confident individuals will be fully empowered by PHS service to care for their health and engage into symmetric relations with healthcare professionals, whose intervention will be reduced in a context

Table 5: From gaps to research domain and preliminary themes

Research domains	GAPS	Preliminarily associated research themes
Integration External Knowledge <i>(boxes: 1, 3, 5)</i>	<ul style="list-style-type: none"> Lack of integration of updated clinical evidence, biomedical and genetic information to ensure scientific control, risk assessment, and personalisation Validation of data from uncontrolled conditions (enucleated and moved here from Gap of Box 2) 	<ul style="list-style-type: none"> Integration of up-to-date medical info from bio-banks, trials; Integration of genetic and biomedical information Controlled studies to correlate and compare data obtained in both “clinical settings” and “uncontrolled conditions”(from context aware PHS) to identify normal and abnormal patterns of parameters uses for action/actuation taking into account personal and contextual factors (to be used for correction/rectification)
	<ul style="list-style-type: none"> Need of holistic clinical guidelines and pathways to align PHS delivered care to best practices and to capture the multi-facet nature of health status 	<ul style="list-style-type: none"> software systems integrating and modelling guidelines within PHS
Data processing	<ul style="list-style-type: none"> Lack of capacity to process data coming from different sources and to address the issue of data generated under “uncontrolled conditions”; 	<ul style="list-style-type: none"> Data fusion and multimodality (data processing, interpretation and modelling capable of simultaneously treating vital and physiological signs, genetic, biomedical, and contextual parameters such as individuals activities, location, emotional status, external environment; Correction/rectification techniques to normalise data gathered under “uncontrolled conditions”
<i>(boxes: 2, 4, 13)</i>	<ul style="list-style-type: none"> Lack of capacity to recursively learn from individuals specific characteristics and context and automatically adapt data processing to personalise monitoring and enabling actuation reducing the need of healthcare professionals intervention 	<ul style="list-style-type: none"> Auto-adaptive and data fusional algorithms and related prediction and modelling techniques; Development of automatic calibration
	<ul style="list-style-type: none"> Lack of personalised aid decision tools for users 	<ul style="list-style-type: none"> Development of simulation tools based on holistic data processing (see above) and easy imaging and visualisation (see VPH related themes)
Interfacing & Interaction	<ul style="list-style-type: none"> Lack of multi-channel delivery and inter-action creating risk of exclusion due to lack of access to, or confidence in, PHS typical interaction channels 	<ul style="list-style-type: none"> Development of multi-channel delivery and inter-action systems including more commonly used devices (i.e. mobile, Digital TV, etc.)
<i>(boxes: 6, 10, 11, 12)</i>	<ul style="list-style-type: none"> Need of more understandable and easy to interpret input and guidance to users; Need to better inform and educate PHS users 	<ul style="list-style-type: none"> Development optimal and easy-to-use interfacing techniques; Development of straightforward imaging; Development of PHS related e-Learning and web2.0 tools

Research domains	GAPS	Preliminarily associated research themes
Sensors <i>(boxes: 4, 7, 8, 9, 14, 15, 16, 17)</i>	<ul style="list-style-type: none"> • Lack of capacity to capture new signs on the environment (both physical and chemical parameters) and on the peculiar situations of individuals (activity, location, emotional status) • Monitoring techniques not able to correctly link physiological signs, with motions, gestures, and environmental data; 	<ul style="list-style-type: none"> • New sensors for context awareness (environment, emotional status, punctual location and situation, etc) and for gathering data in “uncontrolled conditions”; • Investigate out to incorporate data from environmental sensors • Incorporation of advancements in human-computer interfaces and ambient intelligence (in order to “read” emotions though facial expressions and gestures, see later) • Incorporation of on- board processing
	<ul style="list-style-type: none"> • Need to go beyond the “one sensor- one signal” and “one sensor- one disease” paradigm to optimise energy and bandwidth usage • Need to simplify and reduce the amount of data transfers • Need to increase flexibility and better adapt the sensors to individual characteristics (reduce invasiveness and consider allergies) 	<ul style="list-style-type: none"> • Optimisation of multi-modality to insure multi-disease and multi-signal assessments • Self-calibration of sensors • Optimisation of sensors area networks and modularisation of components (plug & play)
	<ul style="list-style-type: none"> • Lack of knowledge on the long term effect of sensors contact with, and presence in, the human body; • Lack of closed loop systems moving PHS beyond monitoring and into diagnosis and treatment (i.e. dispensation and reaction): <ul style="list-style-type: none"> ○ Actuators in general ○ Personalised drug delivery ○ Endoscopy capsules 	<ul style="list-style-type: none"> • Integration of researches on alternative sensors’ materials (e.g., biological and molecular sensors) • New smart sensors encompassing multimodality, computational power and actuation functionalities (including alternative energy sources: i.e. body energy) • Incorporation of controlled drug delivery sensors (implantable and minimally invasive)
Lab on Chip <i>(boxes: 18, 19, 20)</i>	<ul style="list-style-type: none"> • Avoid fragmentation of testing and the need of traditional lab tests to complete Point Of Care (POC) testing 	<ul style="list-style-type: none"> • Investigation on including multiple biomarkers on a single chip • Research on “new” biomarkers more adapted to POC; • Integration of Micro-Opto-Electro-Mechanical-System (MOEMS)
	<ul style="list-style-type: none"> • Reduce human intervention in sample preparation; 	<ul style="list-style-type: none"> • Development of on-board sample preparation; • Further research on micro-fluidic techniques optimising “sample course control”;

Research domains	GAPS	Preliminarily associated research themes
	<ul style="list-style-type: none">• Reduce time to result;	<ul style="list-style-type: none">• Optimising of fluidic control and run-time;• Further research on alternative array technologies adapted to POC-solutions

where the healthcare sector will be open to a multitude of players as the public actor will limit its role to that of steering but will reduce its production function. On the contrary the “Caring State” will retain control over the healthcare sector but will heavily rely on PHS solutions, especially for prevention, early detection, lifestyle management with a strong emphasis on compliance to prescriptions and guidelines and sanctions on moral hazard and opportunistic behaviours.

As a result of the combined reading through these two lenses an additional important issue emerged that we can call “*Energy Efficient and Environmentally Friendly PHS*”. First, if PHS have to be truly personalised and user friendly they must use minimally or non invasive devices and minimise constraints on user normal life, which means wireless and mobile systems. Both of these two requirements raise challenges of optimisation of energy and bandwidth consumption. Second, if we look at this from the perspective of scenarios envisaging large scale deployment and usage of PHS, then the issue of energy efficiency become a must from a macro socio-economic perspective as does the need of reduce waste disposal and pursue the environmental sustainability of PHS.

The gap where the thread of personalisation and the input of the two cited scenarios are most clearly entwined is that stressing how *current PHS applications lack integration with clinical evidence and with bio-medical and genetic information*. Clearly there is probably nothing more ‘personal’ than our genes, and **genomic information** could greatly enhance the goal of personalised treatment, if combined with other information about phenotypes (i.e. vital and physiological signs) and about the environment. Yet, this gap also reflects the concern that, if PHS applications reach large scale deployment and usage, they must be scientifically controlled and be constantly fed with updated clinical evidence. This latter aspect is also reflected in the gap about the need for PHS to incorporate holistic (i.e. across specialities and tiers of healthcare) clinical guidelines and pathways to ensure that eventual treatment match the very specific conditions of each unique individual and the multi-faceted nature of diseases (i.e. in particular co-morbidities for chronic patients).

Whereas in earlier versions of this report we captured these issues only marginally as part of the data processing sub-system, the input received in Barcelona and during the 5th ESC meeting led us to consider them as part of research domain in its own right. We termed this domain “Integration of External Knowledge”, to convey the idea of PHS incorporating input from biomedical and genomic research and from clinical practice (main gap summarised in Box 1, p. 20). In this domain we included also the gap related to the need of new and innovative Decision Support Systems for healthcare professionals, which envisages the integration between PHS and VPH (as illustrated in Box 5, p. 26). Even in this case the gap partly responds to the need (and possibility offered by advancements in VPH) to provide a more personalised visualisation and simulation/modelling of individuals conditions and partly to better endow professionals with appropriate tools to cope with future more empowered users’ demanding the symmetric and possibly negotiating relation depicted in the “Self-Caring Society” scenario. Finally, under this domain we included the gap about the need of PHS of being informed by holistic guidelines (Box 3, p.24).

Evidently, the additional clinical and bio-medical /genetic information incorporated into PHS would need to be processed and interpreted. In the same way the innovative DSS tool would need to be based on predictive and monitoring capabilities, and also holistic

guidelines are in clear relation with issue related to the processing of data. In this respect, then, it is evident that there are clear overlaps between issues placed under the “**Integration of External Knowledge**” research domain and those included within the “**Data Processing**” one.

The issues of making PHS more personalised is tackled in most of its dimensions under the *gap on auto-adaptive and self-calibrating data processing* (Box 2, p. 22) for it deals with the capacity to process a variety of different data recursively as to learn and adapt to the very peculiar characteristics and punctual situations of each individual. In this respect, although presented separately, the gap about *PHS currently lacking techniques able to correctly link physiological signs with motions, gestures, and environmental data* can be considered as a sub-issue of the one on auto-adaptive and self-calibrating algorithms.

Another issue overlapping the “Integration of External Knowledge” and the “Data Processing” domains is that concerning the treatment of data gathered under “**uncontrolled conditions**”. This has implications from a clinical practice perspective and clearly relates “Integration of External Knowledge” domain, but it also concerns data processing technicalities: while input from trials comparing data gathered both in clinical settings and under uncontrolled conditions will be needed, in the end the solution rests within data correction and rectification solutions. Accordingly we enucleated this element from the gap described in Box 2 and included in different ways in the two research domains.

Following the thread of personalisation further we can see clear links (and partial overlaps) also between the “Data Processing” and “Sensors” research domains. It is evident that intelligent data processing combining the various different parameters mentioned so far can be accomplished only inasmuch as the *gap stressing the need of sensors monitoring different kinds of signs ensuring context awareness (external environmental factors, situational activities and location, emotional status) is addressed* (Box 7, p. 28).

Such new sensors would also be fundamental to tackle the issue of data gathering under uncontrolled conditions. This gap has also clear overlaps with that calling for better techniques to correctly link physiological signs, with motions, gestures, and environmental data (Box 4, p. 25).

On the other hand, we can identify also a different link from data processing to sensors in that self-adaptivity and self-calibration of algorithms is a pre-condition for actuation, which is the object of three other gaps related to sensors (see Box 15, p. 34; Box 16, p. 34; Box 17, p. 35).

Moreover, self-calibration is an issue associated also to several sensors related gaps (i.e. Box 7, p. 28; Box 8, p. 29; Box 14, p. 33).

All of the six gaps related to sensors (Box 7, Box 8, Box 9, Box 14, Box 15, Box 16, and Box 17) envisage the opportunity and potential of incorporating on-board processing, and in some cases also actuation, within the sensors themselves. If this occurs, the conceptual distinction between data processing and sensors ceases to be relevant and all of the various research themes overlap.

Now considering only the sensors research domain we can identify three sub-groups termed below using the main research direction they suggest:

- Context and emotional awareness
 - Need of sensors monitoring different kinds of signs ensuring context awareness;
 - Lack of monitoring techniques able to correctly link physiological signs and motions, gestures, and environmental data
- Sensors multi-modality and networks
 - Low possibility to adapt PHS components to individual characteristics (architecture, plug and play, on board processing) ;
 - Lack of multi-signs/multi-disease sensors (multi-modalities, self-calibration, architecture, plug and play, on board processing)
- Materials and functionalities (actuation)
 - Lack of data on long-term effects of contact between human body and sensors
 - Lack of actuators
 - Personalised drug delivery and compliance
 - Endoscopy capsules

Also in this case we are proposing a conceptual simplification of what in practice is a more complex and entwined matter. Sensors for context and emotional awareness may also be integrated into sensors network and would benefit from the advancements envisaged there (on board processing, multi-modality, and self-calibration). The same also applies also for the third group of gaps, whose main research theme associated is about materials and functionalities. On the other hand, new materials and functionalities are also relevant for the gaps associated to context and emotional awareness and to sensors networks as main research themes.

Next we can group together a number of gaps also related to personalisation but from a slightly different angle. In the context of most of the previous gaps personalisation referred to the capacity of data gathering and data processing to capture the very specific characteristic and conditions of each single individual in order to produce personalised monitoring, diagnosis and treatment, in other words we considered the ‘production’ or “back-office” side of PHS personalisation. The following gaps, which we group under the research domain termed “Interfacing and Interaction”, address personalisation from the perspective of users’ experience, in other words users’ fruition of, and interaction with, PHS as services, and also from the perspective of the broader matter of health awareness. Also in this case the various future scenarios elaborated have played a role in eliciting these gaps, and in particular the “Self-Caring Society” one. First, a possible negative effects of this scenario is that it would produce further exclusion of those groups in society less digitally connected and less confident with the use of technology and capable of understanding its input. Second, consumerist attitudes toward health and independent self-caring activities can produce negative results if users access uncontrolled source of health information and/or are not adequately educated in health matters in general and on the various aspect of the PHS applications they will use in particular. From these two risks four gaps emerged. First, to counterbalance the risk of PHS being a source of exclusionary processes, the gap *PHS must address is the harnessing of new*

technological solutions ensuring multi-channel interaction and including also channels more accessible and easy to use (i.e. mobile and/or digital television) for less technology confident individuals (see Box 11, p. 31). Second, assuming individuals use PHS services through their preferred channel, a second *gap stresses the need for PHS to deliver to users input and indications that are intuitive and easy to use through state of the art imagining and visualisation techniques* (see Box 6, p. 27). Third, in order to at least try to channel health consumerist individuals toward correct information and decisions a third *gap calls for the production of quality controlled Web 2.0 tools on matters related to PHS (see Box 12, p. 32).* Finally, a fourth *gap suggests the opportunity to embed within PHS application eLearning modules for users (see Box 10, p. 30).* Regardless of the scenario that originated them, all of these four gaps are highly relevant for the issue of user acceptance and correct use of PHS, which we have shown in the report on scenarios (see D3.1) to be one of the most important barriers to be overcome for these services and more in general eHealth application to take off and fully realise their potential.

Also for the gaps within the “Interfacing and Interaction” domain we can pinpoint some overlaps and links with those of other research domains. First, addressing the two gaps about quality controlled Web 2.0 tools and PHS embedding eLearning modules would require the input and expertise of healthcare professional and, thus, could also be seen as part of the “Integration of External Knowledge” research domain. Second, there is a clear overlap among the following three gaps (the last of which we have not yet included under any of the identified research domains):

- Need of imaging and visualisation techniques for intuitive and easy to interpret input (Box 6, p. 27)
- Need of innovative and holistic DSS for healthcare professionals based on prediction/simulation/visualisation (Box 5, p. 26);
- Need of intuitive patient decision aid tools (prediction and simulation) (Box 13, p. 32).

As we anticipated already in its gap storyline, the development of new and innovative DSS for healthcare professionals based on the integration between PHS and VPH could have positive overspill for users precisely by producing intuitive imagining and visualisation. If this occurs, then these will become DSS shared between the healthcare professionals and patients/users, making thus redundant the gap reported in the last bullet point about “patient aid decision tools”. This latter gap, however, emphasise the modelling and processing of data and could then be retained as part of the “Data Processing” domain.

The final research domain identified is that of “Lab on Chip”, under which fall the following three gaps:

- Avoid fragmentation of testing and the need of traditional lab tests to complete Point Of Care (POC) testing (Box 18, p. 36);
- Reduce human intervention in sample preparation (Box 19, p. 37);
- Need Reduce time to result (Box 20, p. 37).

The synthetic and synoptic view presented in Table 5, which after the considerations so far requires no further comments, constitutes the consolidated platform upon which the roadmapping consultation event will be organised and run.

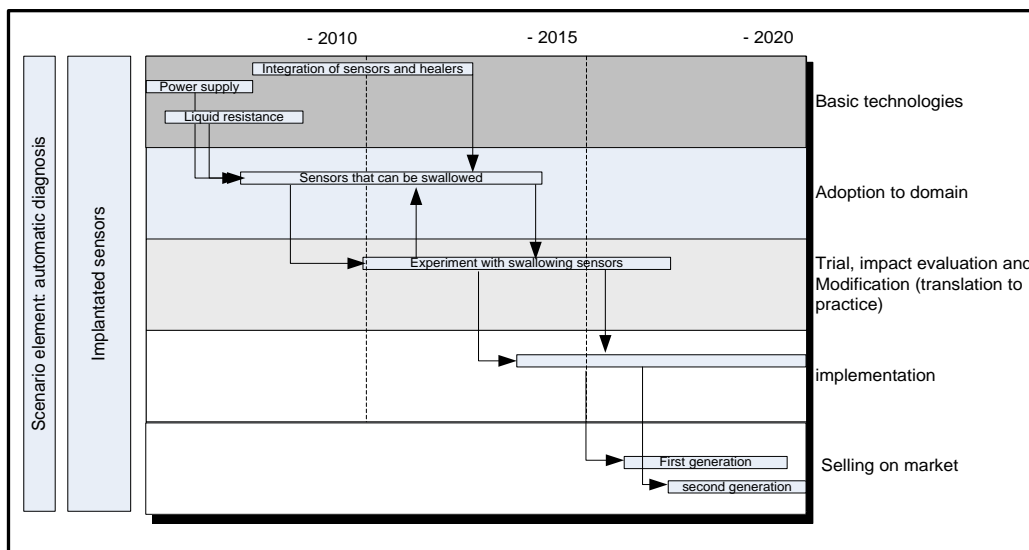
4.4 Roadmapping

The Gaps should directly lead to research themes to be included and structured into a roadmap which for each theme may include the analytical and synthetic output exemplified by the table and figure below

Table 6 Example of roadmap theme: analytical

No.	Description	Means	Players	Timeframe
1	Scoping the problem. <ul style="list-style-type: none"> What is at stake? Evaluating existing research 	Support Action / Tendered study (desk research, in depth interviews, case studies)	socio-economic and technology experts	2009-2010
2	<ul style="list-style-type: none"> Research on power and liquid endurance ... 	Technology R&D (STREP)	Research, ICT industry	2011 – 2013
3	Continue and improve research: <ul style="list-style-type: none"> to produce secure and resistant implantable that are actuators; Enable their communication Study long terms effects 	Technology R&D (IP)	Research, ICT industry, healthcare research and providing institutions	2013-2016
4	<ul style="list-style-type: none"> Pilot and develop measurement system Benchmarking 	Implementation (studies, CIP)	various	2017 – 2020

Figure 2 Example of roadmap theme: visual



The main steps still needed for the roadmap, to be achieved mainly through the consultation event and the re-elaboration and consolidation of their input by the project team, are

1. ***Assess and prioritise the identified gaps.*** The participants will be provided with a very short and brief questionnaire to score the gaps while the brainstorming discussion on them is ongoing. As part of the discussion they can also add new gaps and also assess them. At the end of the various workshop a consolidated list of prioritised gaps all assessed as highly relevant will be produced.
2. ***Identify and develop research themes and actions.*** Group discussions in the workshops will be used to develop important themes for future research in PHS. Groups will be formed based on their interest and expertise and given the task of proposing research themes and related actions only on a limited set of gaps not all gaps . For the most important research themes, research actions and means of implementing the actions must be formulated.
3. ***Phasing the proposed research themes and actions.*** The proposed research actions will be phased into a time scale of short-term (2009-2010), medium term (2011-2015) and long term (2016-2020) actions.

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Annex I: Procedure for gap assessment

As mentioned in the previous chapters, the long list of 56 gaps presented in paragraph 3.2 was illustrated and discussed during the PHS2020 Consultation Workshop held in Barcelona, on September 26th 2008, and during the final ESC Meeting held in Milan, on October 10th.

Participants were asked to assess the full list of 54 gaps organised in three tables, according to the general framework adopted for their presentation.

Table 7 Assessment of GAP full list: Macro Environment

Dimensions	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please indicate for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
Society: demography and general health situation	Rising Chronic diseases prevalence	1. First generation PHS have yet little market penetration;		
		2. Second generation PHS still miss calibration, optimised sensor power supply, multiples signs sensors, multi-modal analysis and fusion		
	Co-morbidities of chronic disease implication for both management and early detection	<u>Integrated care processes and delivery</u> 3. Little integration of care delivery process across healthcare tiers (primary, secondary, etc)		
		4. Knowledge and information segmented and domain-specific		
		5. Lack of robust ICT infrastructure: lack of shared platform for data repository and exchange		

Dimensions	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please indicate for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
		<u>Disease Management</u> 6. Insufficient integration of sub-systems resulting in high bandwidth requirement and power consumption		
		7. Lack of multi-signs/ multi-disease sensors		
		<u>Early detection</u> 8. Encompassing biomarkers per lab-on-chip are limited to 2-3		
		9. PoC sample handling and preparation still, in most cases, requiring human intervention		
		10. Time to result is still too long		
	Long-term care	11. Need of holistic PHS rehabilitation solutions;		
		12. Need of holistic PHS monitoring solutions		
	Neuro-psychological disorders	13. Lack of research on how to acquire data on emotional status and social interaction		

Society: Cultural attitudes and inclusion issues	ICT supported consumerism	14. Need to prepare healthcare professionals for more symmetric relations with citizen/patients		
	Moral hazard and fatalism	15. Need of cogent incentives backed by sanctions		
	Low confidence in/access to ICT	16. Need of education campaign and integration between eHealth and eInclusion policies		
Economy	Energy crisis	17. Need of energy efficient PHS sub-systems and components		
	Environmental sustainability	18. Need to reduce PHS waste and disposal		
Governance	Standard rule setting (steering)	19. Lack of clear legal framework		
		20. Lack of bodies setting bindings standards on inter-operability, protocols, pathways and clinical guidelines and stakeholders for a (including industry) at both national and EU level		
	Financing	21. Institutional reform		
	Prevention & Compliance Focus	22. Need to increase investment of public funds		

Table 8 Assessment of GAP full list: Transactional Environment

Dimension	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
Healthcare professionals attitudes/needs	Awareness/skills	23. Awareness campaigns, education, training,		
	Confidence and concerns about patient safety	<u>Scientific control</u> 24. Lack of integration of clinical evidence, and of bio-medical and genetic information		
		<u>Long term effect of sensors</u> 25. Lack of data on long-term effects of contacts between human body and sensors of different materials especially for implantable (e.g., toxic effects)		
	Decision support & guidance	26. Need of innovative DSS for healthcare professionals based on prediction/simulation/visualisation		
27. Need of PHS software embedding guidelines and pathways (software systems coordinate the activities of all the health professionals responsible for the treatment of a patient and aligning delivery to best practice guidelines)				
Healthcare Delivery and PHS	Integration of patients' data	28. Lack of shared infrastructures and standards for data exchange		
		29. Lack PHR inter-operability even at national level, gap relevant also for industry		

Dimension	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
	Prevention	30. Lack of business model		
		31. Lack of consolidated cost/benefit evaluation methodologies		
	Early detection, screening and profiling	<u>Screening and profiling</u>		
		32. Lack of large enough databases for genetic mass screening of population		
		33. Need of legal framework and consensus		
	Compliance	34. Alarm function and reminders are patently insufficient to ensure compliance		
		35. Need of closed loop solutions monitoring dispensation/reaction calling for all encompassing sensors		
		36. Need of more comfortable and less invasive sensors		
		37. Need of innovative measurement systems to support outcome-based reimbursement based on integration between PHS generated data and larger public health databases		

Dimension	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
3 rd Party Payer	Outcome-based reimbursement	38. Lack of tailoring of security and encryption techniques for healthcare sector application		
Industry perspective	Standard / privacy and legal framework / inter-operability	39. Need of data management and mining applications integrated into PHS that embed, support and protect privacy (also relevant for users & PHS, will not be repeated)		

Table 9 Assessment of GAP full list: Users and PHS

Dimension	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
Awareness, trust, access and use	Awareness and trust	<u>Information campaign</u> 40. Off and online information (on scientific reliability, privacy issue, benefits, etc)		
	Access	<u>More widespread and accessible channels</u> 41. Lack of PHS services delivered through Digital TV (way more diffused among the elderly and other less technologically sophisticate segment of the population and more intuitive than other channels)		
	Interfaces/interaction	<u>Facilitating use</u> 42. Need of PHS embedded eLearning		

Dimension	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
		43. Need of imaging and visualisation techniques for intuitive and easy to interpret input		
		44. Need of new technological solutions (possibly 'invisible) enhancing development and implementation of multi-channel interaction systems		
Comfort, Acceptance, personalisation	Comfortable devices for acceptance	45. Lack of "soft" and "invisible" devices that, however, ensure reliability of data gathered (i.e. wearable)		
	Implantable	46. Implanted sensors gather data and actuate but do not communicate and cannot be monitored		
	Personalisation	47. Need of auto-adaptive algorithms, able to autonomously adjust clinical parameters to individuals' conditions customise		
		48. Need of sensors monitoring different kind of signs ensuring context awareness		
		49. Development of modelling techniques able to correctly link physiological signs and motions, gestures, environmental data		
		50. Need of ubiquitous services distributed across territory and of large processing capability into small and easy to carry/wear devices		

Dimension	Issues	GAPS	Please assess gap importance on a scale 1= low and 5=high	Please for which of the following the gap is more relevant New research (insert 1); Existing research (insert 2); Implementation issues (insert 3)
		51. Need of intuitive patient decision aid tool (prediction and simulation)		
		52. Need of quality controlled web 2.0 tools		
		53. Need of citizen owned fully interoperable Personal Health Records (PHR) integrated with PHS		
		54. Possibility to adapt PHS components (e. g., sensors) according to individuals' characteristics, including, materials (due to allergies, for instance), position on patients' body, etc		

In particular, participants to consultation events were asked to express their evaluation about the gaps according to two dimensions:

- **Importance** of the gap for the future development of PHS, on a scale from 1 to 5 (where 1 was the lowest and 5 the highest level of importance); and
- **Type of action needed** for filling the gap, i.e., new technological research, continuation of existing technological research, implementation.

The main purpose of the assessment exercise carried out was to help the research team in refining the gaps list, identifying issues and themes for further technological research, and separating them from implementation aspects.

From this assessment, only gaps associated with high importance and needing new technological research or continuation of existing research were taken into consideration for further elaboration in the roadmapping process. When elaborating the results, these two conditions were formalised in quantitative terms. Importance was assessed considering the average assessment: only those gaps having an average assessment over the average (i.e., equal to or over 3.5) were considered. In order to define whether a gap should be associated to research or implementation we calculated the mode: only gaps with a mode of 1 or 2 (values associated with new technological research and continuation of existing technological research) were taken into account. However, in order to select the most relevant and significant gaps, both conditions had to be satisfied simultaneously. Hence, only those gaps assessed as important (i.e., with an average value of importance equal to or above 3.5), and in need of new technological research or continuation of existing one (i.e., mode of 1 or 2) were short listed.

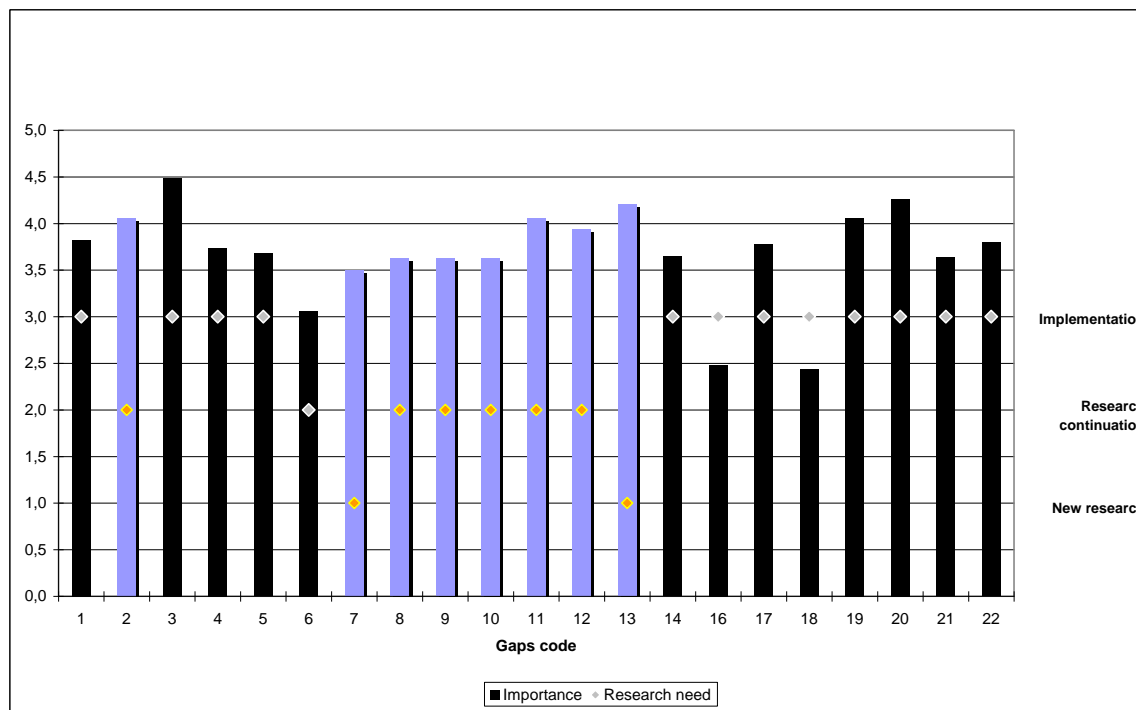
The questionnaires for assessment were submitted to participants in two events, namely the consultation workshop held in Barcelona on September 26, and the final ESC meeting held in Milan on October 10. As some of the experts composing the ESC were also present in Barcelona, they were asked to refrain from re-doing the assessment in Milan. Summarising, a total number of 34 questionnaires were gathered for results elaboration.

Before illustrating and briefly commenting the results of the assessment exercise, it is worth to point out that, during the events concerned, socio-economic and infrastructural conditions (like, for instance, the implementation of interoperable PHRs) were considered and briefly discussed. However, audience was asked to concentrate more on technological issues and development, leaving apart implementation and socio-economic issues.

As a general consideration, it is possible to notice that very few gaps have been considered of low importance and were only slightly below the threshold of 3.5 (only 7 out of 54, i.e. about 13%). In addition, several of the identified gaps received a high score on importance, but were considered as implementation issues (20 out of 54, i.e. 37%). As explained earlier, of the 31 gaps associated to technological research few have been discarded outright but were actually merged with others .

In the following pages, the results of the assessment by macro-dimension of the Descriptive Framework are presented.

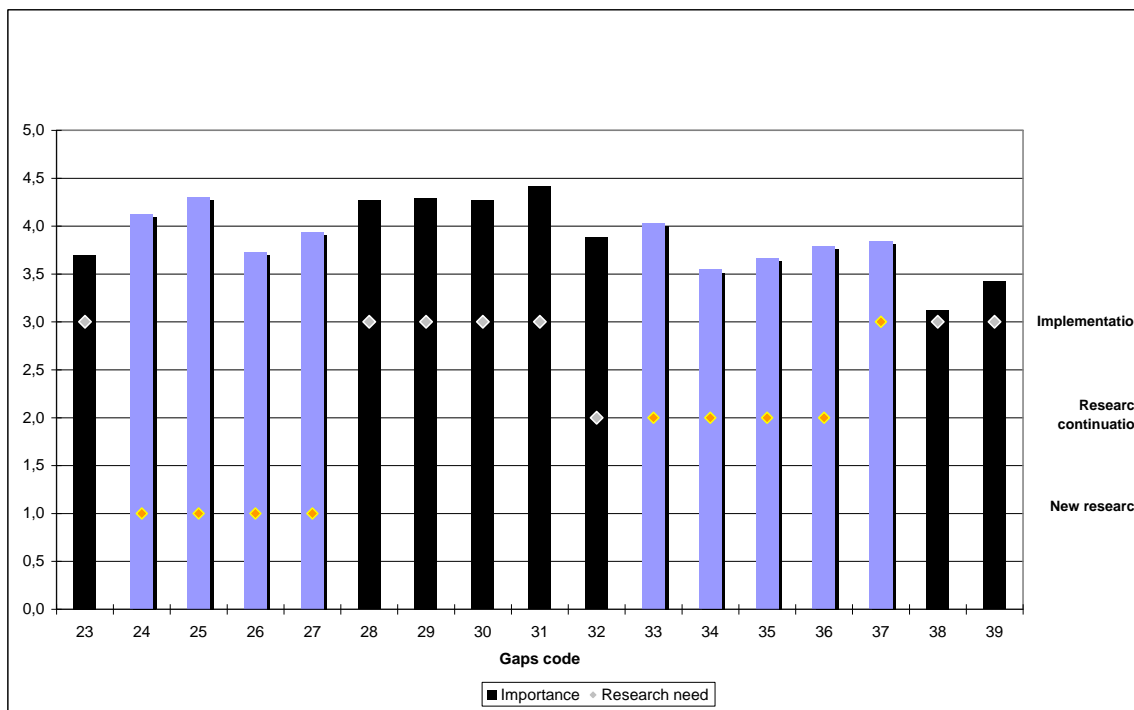
Figure 3: Results of gaps assessment for macro socio-economic environment



Source: Authors' elaboration from gaps assessment questionnaires

As it shows from the figure above, a limited number of gaps (8 out of 54; almost 15%) from the macro socio-economic environment have been assessed as relevant, and therefore included into the restricted list. This can be explained by considering that those gaps mainly related to large social and economic issues, not directly linked to technological research, which instead was the main focus of the assessment.

Figure 4: Results of gaps assessment for transactional environment



Source: Authors’ elaboration from gaps assessment questionnaires

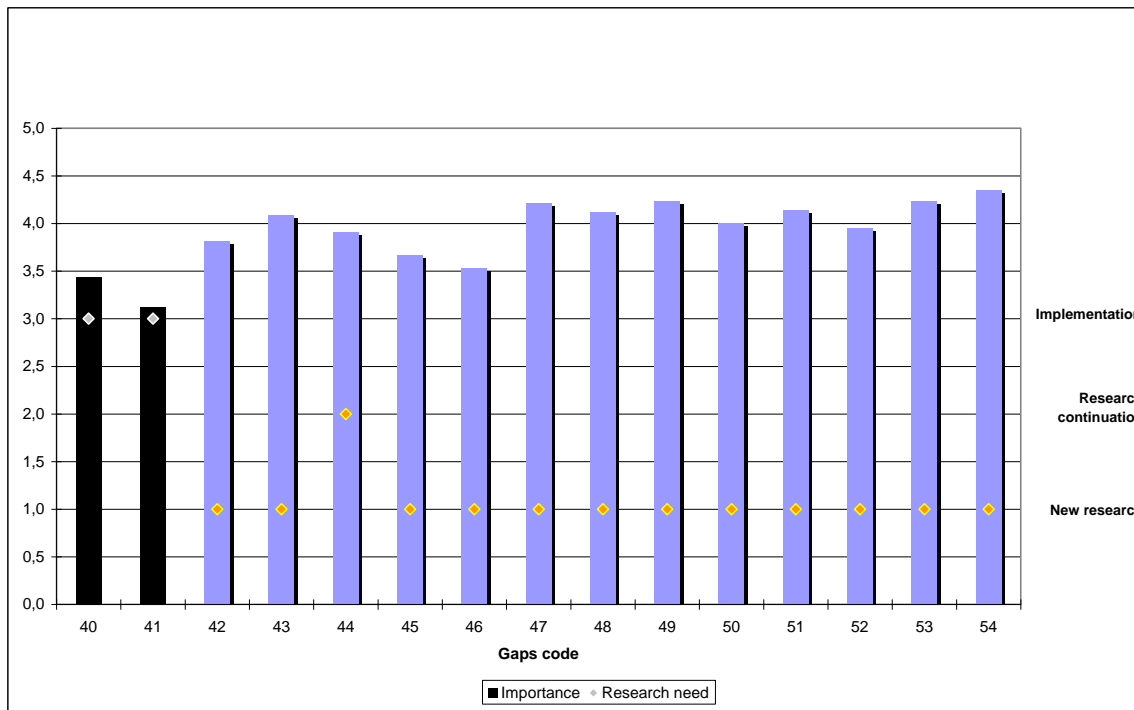
When considering the gaps presented in the transactional environment dimension, the number of those assessed as relevant and included in the restricted list is higher than in the previous group; 9 out of 17 (i.e., almost 53%).

In addition, it is possible to point out how also the number of gaps assessed as needing of new technological research is quite high; 4 out of the 9 gaps selected (i.e., 44.44%), in comparison with 25% in the previous group (2 out of 8).

Another consideration can be done with regard to the assessment in terms of importance of the presented gaps. Only 2 out of 17 were considered as “non important” (i.e., with a average assessment lower then 3.5), representing about 12%, with a slight decrease from the previous group (3 out of 22, i.e. 13.63%).

The higher number of “relevant” gaps with respect to the macro socio-economic environment can be explained by the fact that this groups encompasses issues more related to actual deployment of PHS application and the actors involved. Such issues, therefore, have stricter inter-dependencies with technological advancements than with a supportive environment for PHS, requiring in larger measure technological research.

Figure 5: Results of gaps assessment for Users and PHS



Source: Authors’ elaboration from gaps assessment questionnaires

As illustrated by the figure above, almost all (13 out of 15; i.e., 86.67%) of the gaps presented in this groups were assessed as “relevant”, i.e., important and needing new technological research or continuation of new one.

Moreover, the almost all of those selected for the restricted list (12 out of 13; almost 93%) are considered as needing new technological research. Of these, 8 out 12 had score for importance higher then 4.

It is noteworthy to point out how the main parts of those gaps were related to interfaces and interaction between users and PHS, and on personalisation of PHS, including issues like context awareness, interpretation of different signals and status (including psychological and emotional status), actuators, etc. In addition, other gaps selected focused on improving users’ education and awareness about their health status, and on providing them support in terms of more knowledge and motivation.