

iNOVAHEALTH

Cyprus EU Presidency

Building an Open Innovation ecosystem in Europe for healthcare

Recommendations to incentivise an Open Innovation culture and environment to promote economic growth, increase employment and reduce healthcare costs

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1. Executive Summary

The sustainability of European healthcare systems is under threat – the ageing of the European population, the prevalence of chronic disease and a need to focus on wellness and preventative health management, in parallel with treatment of disease, pose significant social and economic challenges. The current economic situation has made these issues more acute. In addition, many healthcare-related industries have reduced their Research & Development (R&D) bases in Europe and intellectual property generated within the European Union (EU) is frequently commercialised elsewhere. Europe still has significant strengths in healthcare – a strong academic base and industrial leadership in areas such as pharmaceuticals, medical devices, mobile technologies and diagnostics as well as a strong public healthcare ethic. Initiatives in Open Innovation like the Innovative Medicines Initiative and the recently launched European Alliance for Personalised Medicine (EAPM), have shown that Europe can capture and capitalise on collaborations between industry, Small Medium Enterprises (SMEs), academia and other stakeholders in the healthcare system to create intellectual and economic impact. Europe is now uniquely placed to build on these competitive advantages to create an Open Innovation ecosystem for healthcare, which would promote economic growth, increase employment, improve citizen centric health and wellness and reduce healthcare costs.

Regulation needs adapting, research needs encouragement, new approaches are needed to allow for innovation, and training of healthcare professionals and awareness among patients and the public need to be boosted. European health care systems will need to take a more sophisticated view of health care that goes beyond merely responding to acute episodes associated with single illnesses¹.

The iNOVAHEALTH strategy provides an Open Innovation roadmap to create an integrated and interdependent environment (ecosystem) where companies, scientists, policymakers, governments, patients and other organisations can interact productively to promote radical change and innovation in healthcare supported by new developments in information and communication technologies (ICT). The aim is to create sustainable, affordable, citizen centric healthcare systems, which leverage new technologies whilst at the same time stimulating the EU economy and creating new employment opportunities

Key recommendations

To create an Open Innovation health and wellness ecosystem the EU should:

- To establish a new Public-Private Partnership under Horizon 2020 focused on common industry and public health needs, building on the achievements of and lessons learned from IMI
- Create a cross directorate task force within the European Commission to address the barriers to establishment of this Open Innovation healthcare ecosystem through a partnership centred approach.

To create an European Health Institute aiming at integrating the different actions from multiple stakeholders that are needed to empowering citizens to be at the heart of healthcare across the European Union

- Use the upcoming industrial policies (as announced in the Commission **Update of the Industrial Policy flagship initiative – “A Stronger European Industry for Growth and Economic Recovery”, 10th October 2012**) to develop the concept of “lead markets” for life science innovation.

¹ EAPM Manifesto - <http://img.euapm.eu/resources/eapmmanifesto.pdf>



Methods used to create iNNOVAHEALTH strategy

A task force was established under the Cyprus Presidency from key industrial and other stakeholders (see below) to produce and draft document and recommendations.

In October 2012, a conference was held under the Cyprus presidency where the strategy was presented and discussed in a series of workshops. The final document incorporates comments and revisions in light of the workshop and from its participants.

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2. Introduction

In 2011 the EU Commission held the second in a series of stakeholder meeting on the challenges of innovation in healthcare in Europe ¹. The meeting stressed that innovation is not only concerned with new technologies and products but also about people, behaviour and the need for a change in mindset of all stakeholders to enable innovation to thrive. Importantly it highlighted the unique potential for innovation in healthcare not just to drive economic growth and job creation but also in terms of reducing the healthcare costs and improving patients' quality of life.

Approximately a tenth of the EU's GDP is spent on healthcare and over 15 million people are employed in Europe in this sector. Some examples of disease burden in Europe are listed below with further examples given in individual chapters:-

- There is a €800 billion annual cost of brain disorders in Europe, with brain disorders affecting 1 in 3 of the population (European Neuropsychopharmacology (2011) 21, 718–779)
- Almost 400 million adults in the region are estimated to be overweight and about 130 million, obese. Obesity creates a major economic burden through loss of productivity and income, and consumes 2-8% of overall health care budgets (WHO).
- Cancer in Europe affects 1 in 3 men and 1 in 4 women at some time in their lives. It is estimated that 1.2 million EU citizens die from cancer each year ([Public Health Portal of the European Union](#)).
- Each year Cardiovascular Disease causes over 4.3 million deaths in Europe and over 2.0 million deaths in the European Union (EU) with a cost to the EU economy €192 billion a year. ([European Heart Network](#)).

The proportion of the population of Europe that is over 60 years old is also increasingly bringing additional burdens on healthcare budgets although this is not the sole cause of the increased per capita healthcare costs in the EU member states. According to the Eurostat data, on average, life expectancy at birth for the three-year period 2006-08 stood at 76.4 years for men and 82.2 years for women in EU-27. Currently the ratio of pensioners to people of working age is 1:4 but by 2050 it will be 1:2 so although the number of elderly people is increasing, the number of taxpayers who will pay for the healthcare systems is decreasing.

In many cases the most significant healthcare impact of this ageing population will be the increasing number of people with multiple chronic conditions presenting challenges in optimising treatment interventions. Likewise, lifestyle patterns (e.g. high alcohol consumption, obesity and smoking) can also have a significant effect on the rates of chronic disease such as cancer, cardiovascular disease and diabetes. Healthcare costs are on average 5 times greater for chronic disease and chronic diseases like diabetes cause multiple health problems requiring a coordination of treatments and a more holistic approach to management. Thus there is even more need to consider both preventative and behavioural approaches to the management of chronic and complex diseases. In order to do this and meet the future challenges of healthcare, Europe must adopt an agenda where healthcare systems are effective, integrated and informed.

There is an urgent need for engagement of a wide range of stakeholders as the success of innovation will depend on a shift in thinking across wide areas of healthcare, and a new form of multi-disciplinary engagement as set out in the EAPM Manifesto that was launched on September 18th by Commissioner Dalli.

Spending on healthcare is clearly increasing, eg France spent 11.8 percent of its GDP on healthcare in 2009, up from 10.1 percent in 2000. The United Kingdom (U.K.) spent 9.8 percent, up from 7 percent in the same period. The United States spends far more on healthcare than any other nation.



In 2009, healthcare costs reached US\$2.5 trillion, or 17.4 percent of GDP, up from 13.7 percent in 2000. Healthcare costs will continue to rise rapidly and relentlessly worldwide. The Organization for Economic Co-operation and Development (OECD) projects that Europe's healthcare systems require spending increases that outstrip economic growth². Yet it is questionable whether increasing spend is yielding improving returns; more needs to be done to rein in costs and improve patient outcomes by encouraging new ways of doing things.

In addition, many non-traditional players are now investing in developments for the health sector. Consumer goods companies are developing health and wellness products, telecommunications companies are investing in remote monitoring systems and medical applications for smart phones have increased dramatically. There are real opportunities from cross sector engagement and collaboration to deliver more efficient healthcare solutions as were very different technologies intersect; the opportunity for transformational innovation is created.

In order to maintain and expand the role of industrial as well as social and academic innovation in healthcare, Europe must not only have a strong healthcare R&D base but also provide a market for the innovations that will emerge.

2.1 Competitiveness of Europe in Healthcare Innovation

Pharmaceutical companies have traditionally been a strong source of innovation in healthcare, providing new medicines and vaccines². The pharmaceutical industry employs over 640,000 in Europe and creates over three times more jobs than that figure indirectly. The industry invests approximately Euros 27B in R&D in Europe alone. However the position of the EU as a place where pharmaceutical R&D investment occurs, has been eroded over the past ten years although Pharmaceutical R&D still accounts for 19% of all private R&D in the EU (EFPIA statistics). Between 1990 and 2008 pharmaceutical R&D investment grew 5.6 fold in the USA but only 3.5 fold in Europe and the latest figures suggest it is not increasing at all. Large corporations such as AstraZeneca and GlaxoSmithKline have reduced their R&D in Europe whilst investing in China and other international locations. In addition, the European market is also challenging and accounts for significantly less sales than the USA in terms of new medicines. IMS Health data indicates that 66% of sales of new medicines launched 2004-2008 were in the USA whereas only 22% were in Europe.

Likewise, the medical device industry makes a valuable contribution to the European economy³ employing over 500,000 people and generating sales of Euro95Billion (B) with an R&D spend of Euro7.6B. Importantly, nearly 80% of the 22,500 companies working in this area are SMEs. Importantly the European market is about 30% of the global medical devices market. In addition the EU has traditionally been strong in other sectors of relevance to healthcare such as the food and nutrition industry (see Chapter 3 for more detail).

The Innovation in Healthcare report identified several barriers to innovation in healthcare in Europe. These included: -

- Weaknesses in the technology transfer capacities
- Access to finance
- Fragmentation of Health technology Assessment (HTA), pricing and reimbursement in the EU member states
- Lack of a framework to aid the development of personalised medicine

Overall it concluded that there was a need to improve the system at all levels. One framework, which could be used to drive the change in mindset and act as an incentive to innovation in a cost efficient manner is that of Open Innovation.



2.2 The Potential of Open Innovation

Henry Chesbrough first coined the term, “Open Innovation” in 2003⁴. In it he defined Open Innovation as: *‘the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively. Open Innovation is a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal, and external, paths to market, as they look to advance their technology’*. Joel West⁵ sees it simply as *‘Open Innovation means treating innovation like anything else - something that can be bought and sold on the open market, not just produced and used within the boundaries of the firm’*.

Historically many companies, especially those in the pharmaceutical industry have operated a traditional, closed model (Figure 1a). In this model a single company has all the means of prosecuting an idea from inception to market and all intellectual property (IP) is retained within the company boundaries. In an Open Innovation model (Figure 1b) there is more dynamic flow of ideas, with the boundaries of the organization becoming much more porous. It is important to note the two-way nature of the interaction in the Open Innovation model. Many companies that claim to have an Open Innovation agenda have concentrated on a uni-directional approach, sourcing from the outside in, instead of a bi-directional approach, where the outflows from an organization are as an important source of innovation as the inflows. As discussed in Chapter 7, incentives are needed to create the right ecosystem for this dynamic interchange of resources and ideas to maximize value creation. A clear example of this in the pharmaceutical sector was the significant stimulation given to the Swiss biotech industry by pharmaceutical spinouts in the 1990s and the development of the Philips High Tech Campus at Eindhoven in the last decade.

As discussed in the following chapters, the time is right for an Open Innovation framework to be adopted for and by the healthcare sector in Europe. The convergence of a number of different industries provides significant opportunities for leverage ideas and IP across a number of different sectors and stimulating innovation. The focus on prevention and wellness in addition to treatment will also require a different mind-set in terms of healthcare delivery and provision and must leverage new technologies in a timely and cost efficient manner, which is also citizen, focussed. At the same time, European best practice guidelines in that field have already been developed and endorsed by the EU Member States. These should be implemented in a timely manner in the different European health systems (www.phgen.eu). Also, new ICT developments in healthcare such as the “virtual twin” provide innovative solutions to personalised medicine and healthcare (www.itfom.eu) putting citizens’ in the centre of future healthcare as supported by key European initiatives such as the newly established EAPM and the IMI. There are however still significant barriers that exist to the adoption of an Open Innovation agenda in healthcare and the recommendations in this report provide suggestions for areas, which should be prioritised, for action to allow Open Innovation to flourish.



Figure 1a)

Closed innovation model

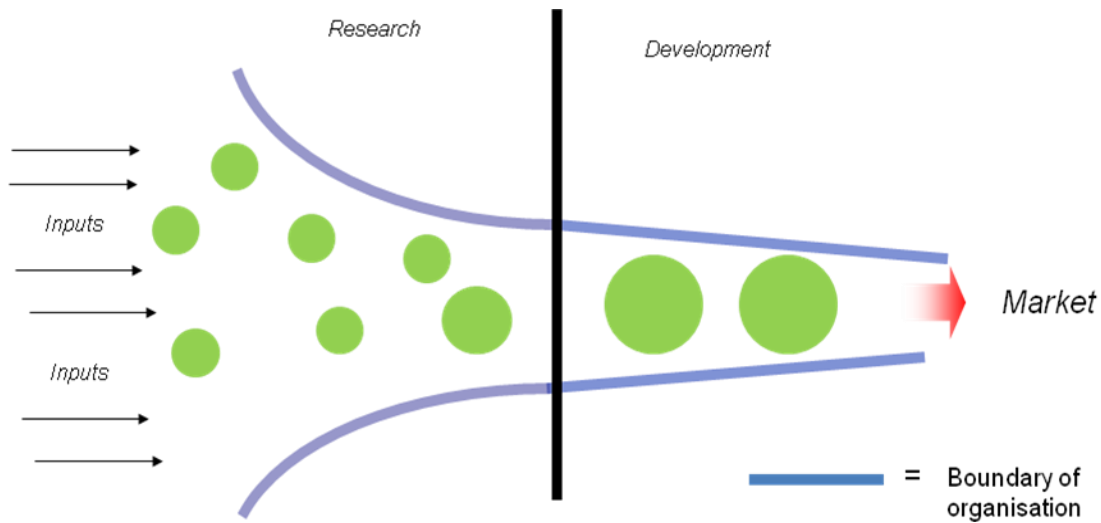
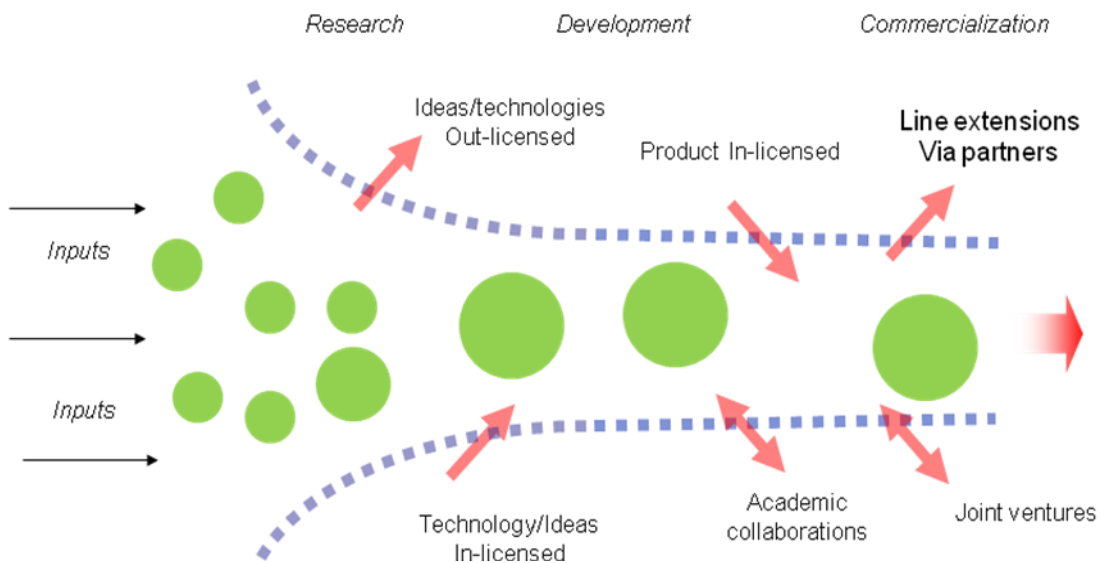


Figure 1b)

Open Innovation model



(After ref 4)

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Chapter 3

Nutrition and Healthcare

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3.1 Nutrition and Healthcare

Nutrition plays a vital role in health and disease throughout life. It is essential for optimal development, survival and for maintenance of health. Furthermore, scientific research and innovative healthcare approaches show increasing potential for the role of nutrition in prevention, disease management and recovery.

During the early phase of life, metabolic imprinting and programming of gene function through nutrition can affect risk of obesity, diabetes, cancer, allergies, autoimmunity and other diseases later in life.

Disease-related malnutrition, particularly in the elderly, is a major public health problem that often goes unrecognized and untreated. In malnourished patients, Medical Nutritional supplements are associated with reduced mortality, less complications, less hospital readmissions and improved rehabilitation (www.medicalnutritionindustry.com 'Oral Nutrition Supplements to Tackle Malnutrition')¹¹. Specialised nutrition, through translation of scientific research into evidence-based practices, provides a powerful tool with which to mitigate the social suffering and healthcare burden of the EU's main health challenges of the 21st century

As an example, brain health is highly sensitive to nutritional influences

- Nutrition influences cognitive development in childhood, psychological conditions in adolescent and adult life, and cognitive decline in the elderly
- Medical nutrition can improve memory in patients with Alzheimer's disease

The Steering Group of the European Innovation Partnership of Active and Healthy Ageing has recommended in 2011 that their primary goal should be to ensure the average European citizen has 2 more active and healthy years to live by 2020. In these recommendations nutrition plays a central role by helping to prevent functional decline and frailty



To enable the paradigm shift from care and cure towards prevention, participation and coaching, an integrated approach is required that includes lifestyle and nutritional factors and calls for alignment between healthcare providers to integrate multiple healthcare solutions. This requires an Open Innovation approach across multiple industries and delivering new business models.

The strong heritage and position of the food and nutrition industry in EU, combined with its advanced medical healthcare, provides an excellent opportunity to create a unique competitive position in Integrated Healthcare.

The following key recommendations need to be implemented with priority:

1. Increase awareness of benefits of nutrition as integrated part of healthcare and stimulate implementation in practice

- Leverage European Innovation Partnership on Active and Healthy Ageing (EIP AHA): *‘Prevent functional decline and frailty, focus on malnutrition’*
- Improve the realisation of health-economic benefits through the application of nutrition as an integral part of healthcare. This should form part of European wide and member state level policy

2. Stimulate cross-discipline approaches to innovation in preventive health, combining early diagnosis, nutrition and therapies

- Study mechanism and course of disease throughout life and focus on early intervention and prevention
- Put the ‘patient’ at the centre of new, integrated healthcare approaches with focus on creating ‘patient value’

3. Ensure market access for evidence-based nutritional solutions to patients and consumers

- Maintain recognised regulatory space for Medical Nutrition (FSMP: ‘Food for Special Medical Purposes’)
- Evolve regulatory frameworks to allow nutritional solutions for early stage intervention as (secondary) prevention

3.2 Role of Specialised Nutrition in Health and Disease Throughout Life

Nutrition plays an important role in health throughout life. Sufficient nourishment is essential for survival and to allow optimal development and growth from the foetus to adulthood, and remains essential for maintaining optimal body function. In the past decades, focus in public health and science has gradually changed from quantitative to qualitative aspects of nutrition, and today it is well recognised that a healthy diet has a massive impact on health. Sixty per cent of mortality is due to chronic diseases that are associated with lifestyle and in these diseases nutrition is a key factor. Consequently, many of the most prevalent diseases or conditions of suboptimal health can be prevented by:

- Improved nutritional intake, either by reduced caloric and/or nutrient intake
- Prevention of nutritional deficiencies
- Meeting the specific nutritional requirements of individuals in a specific age range, or those with specific health conditions/diseases and risk factors through specialised nutrition



The next section provides some key insights and examples illustrating the potential of specialized nutrition to improve health across the lifespan. An overview of the areas where specialized nutrition can have health- and healthcare benefits in the various stages of life is provided in table 1.

3.2.1 Nutrition in the early phase of life – metabolic programming and healthy development

In the earliest stage of life the risk of neural tube defects in foetuses is reduced through the extra intake of the B vitamin folic acid by normally nourished pregnant women. This is one well know and broadly recognized example of the critical importance of nutrition for early life. In general, preconception, pregnancy, lactation and early childhood are the phases in life when nutrition can have a large health benefits in later life e.g. through imprinting and programming of gene function. During these phases the human gene pool adapts to a changing nutritional environment by adjusting gene function via so called epigenetic 'switches' that can be gradually turned 'on' or 'off' via gene (DNA) modifications. Most of these switches are set when cells and organs are being constructed, based on exposure to nutrients. Once the cells and organs are fully developed, the gene function is more difficult to change and essentially set for life. In this way early nutrition exerts lifelong effects on various functions of the body. It has already been demonstrated that the prevalence of obesity, diabetes, cancer, allergies, autoimmunity and other diseases can be affected by metabolic imprinting and programming through specialized nutrition.

3.2.2 Health maintenance in (young) adulthood and healthy ageing

As mentioned in the introduction, excess weight and obesity is an increasing problem which now affect over 50% of the European adult population, and both conditions are important risk factors for type 2 diabetes and cardiovascular disease. Lifestyle modifications, including dietary measures, are more effective than drug treatments in preventing, stopping and reversing obesity and the early development of type 2 diabetes. In an ageing population, this can substantially impact the overall disease burden.

Many diseases of older age are associated with declining mental performance i.e. brain function, and physical performance i.e. muscle function. This decline is an inevitable result of ageing, the rate of decline and disability can be greatly modified by strengthening the muscle mass and “cognitive reserve” in middle age. This may reduce the likelihood of developing physical disability (i.e. a syndrome called sarcopenia) and Alzheimer’s disease, respectively. In particular, recommendations for the management of sarcopenia indicate the use of novel nutritional therapies, such as supplemental dietary protein, specific anabolic amino acids and vitamin D.



Table 1: Potential areas where specialised nutrition can have health/healthcare benefits in various stages of life (early in life, adulthood, ageing and diseased)

Early in life	General health	Prevention (ageing population)	Disease management
<ul style="list-style-type: none"> • Prevention neurodevelopmental disorders • Autism (improve behavioural aspects, gut problems) • ADHD (decrease impulsivity, increase concentration, reduce side-effects, manage co-morbidities, modify disease) • Epilepsy (decrease epileptic attacks) • Cerebral palsy (prevent neuronal decline, prevent epilepsy, improve motor performance) 	<ul style="list-style-type: none"> • Brain/mental health (maintenance) 	<ul style="list-style-type: none"> • Cognitive ageing (prevent cognitive deterioration) • Ageing (remain healthy, stay independent longer, improve QoL) 	<ul style="list-style-type: none"> • Alzheimer's Disease (improve memory and cognition, QoL) • Parkinson's Disease (reduce motor complications, reduce non-motor symptoms) • Neuropsychiatric disorders (e.g. schizophrenia) (reduce symptoms such as psychotic events) • Mood disorders (e.g. depression) • Epilepsy (decrease epileptic attacks) • ALS (slow disease progression and reduce symptoms) • Neuropathic pain (decrease pain) • Sleep disorders • Diabetic neuropathy (reduce symptoms, e.g. paralysis or pain)
<ul style="list-style-type: none"> • Metabolic disorders (e.g. Phenylketonuria [PKU] – prevent neurological impairments) 	<ul style="list-style-type: none"> • Obesity (reduce risk for serious diet-related diseases, including diabetes, cardiovascular disease, hypertension and stroke, and for certain forms of cancer) 	<ul style="list-style-type: none"> • Obesity-related metabolic disorders: • Cardiovascular disease (reduce risk factors, e.g. cholesterol) • (Pre-) diabetes (treat/prevent complications and reduce risk factors, e.g. glucose, lipid profile and blood pressure) (Delay progression to disease) 	<ul style="list-style-type: none"> • Cardiovascular disease (reduce hypertension and atherosclerosis) • Stroke • Diabetes type 2 • Metabolic syndrome (Delay progression of disease and improve QoL) • Liver disease (metabolic capacity)
<ul style="list-style-type: none"> • Body composition and growth (optimise growth and development of sick infants (with, e.g. congenital heart disease, SBS, chronic lung disease, cystic fibrosis) and children (e.g. neurologically impaired, GI disease, cardiac disease) to avoid long-term consequences by promoting catch-up growth and bring children back to the standard growth curve) 	<ul style="list-style-type: none"> • Muscle health (maintenance) • Muscle preservation in weight management • Athletes (improve peak performance) 	<ul style="list-style-type: none"> • Preserve and improve muscle (prevent sarcopenia) • Falls (prevent falls) • Insulin resistance in obesity and diabetes (preserve muscle mass and function, glucose control) 	<ul style="list-style-type: none"> • Sarcopenia (improve muscle strength, physical function, ADL, mobility) • Muscle wasting in acute and chronic disease (cachexia): • Oncology (improve performance status – QoL, chemotherapy efficiency) • Respiratory disease: COPD (improve physical function after rehabilitation) • Recovery after immobilisation: hip fracture, ICU (improve physical function and mobility after rehabilitation) • Frailty: malnourished, hospitalised, institutionalised (improve muscle strength, mobility, ADL, independence, QoL, recovery)
<ul style="list-style-type: none"> • Immune function (maturation of immune system, reduction of gut – inflammation) • Allergy (elimination of food allergens to resolve symptoms and promote growth and development) 	<ul style="list-style-type: none"> • Gut digestion 	<ul style="list-style-type: none"> • Gut digestion 	<ul style="list-style-type: none"> • Inflammatory bowel disease • HIV (manage side-effects of antiviral therapy, support gut-associated lymphatic tissue and intestinal health) • Multiple sclerosis (decrease remissions) • Musculoskeletal disorders: arthritis

ADHD, attention deficit hyperactivity disorder; QoL, quality of life; ALS, amyotrophic lateral sclerosis; ADL, activities of daily living; SBS, shaken baby syndrome; GI, gastrointestinal; COPD, chronic obstructive pulmonary disease; ICU, intensive care unit



3.2.3 Disease management: nutrition as an integral part of therapy

In older age and during disease it is challenging to meet nutritional requirements with conventional foods alone. This may be due to:

- Situations when consumption of normal foods is impaired or impossible, for example following a stroke, surgery or severe trauma
- Impaired uptake and absorption through inflammation and disorders of the gastro-intestinal tract
- Metabolic changes leading to specific nutritional needs, for example due to deficient liver biosynthesis of nutrients

The resulting disease-related malnutrition (DRM) is a major public health problem that often goes unrecognised and untreated. Treatment of DRM with specialised nutrition has been shown to improve measures of physical activity, quality of life and independence. In addition, Medical Nutritional supplements have been consistently linked to lower mortality, reduced complication rates, fewer hospital readmissions and improved rehabilitation in malnourished patients compared with standard care.

3.2.4 Brain health and neurodegenerative disorders

Specialised nutrition, through translation of scientific research into evidence-based practices, has appealing potential for enhancing health across a broad spectrum of physical abilities, conditions and diseases. This chapter will focus on the examples in brain health and neurology, as brain-related disorders are one of the primary clinical challenges in the EU.

The brain is a metabolically active organ requiring a large proportion of total nutrient and energy intake. As such, brain health is highly sensitive to nutritional influences:

- Nutrient enrichment in infants has detectable effects on brain structure and cognitive function almost two decades later
- Nutritional modulation affects cognitive development and neurodevelopmental disorders in childhood, and psychiatric conditions in adolescence and adult life
- Cognitive decline in the elderly is accelerated if there is insufficient intake of the nutrients most critical for brain maintenance and function
- In patients with Alzheimer's disease medical nutrition improves memory performance, one of the core characteristics of the early phases of disease

The potential role of specialized nutrition in cognitive development and decline is summarized in figure 1.

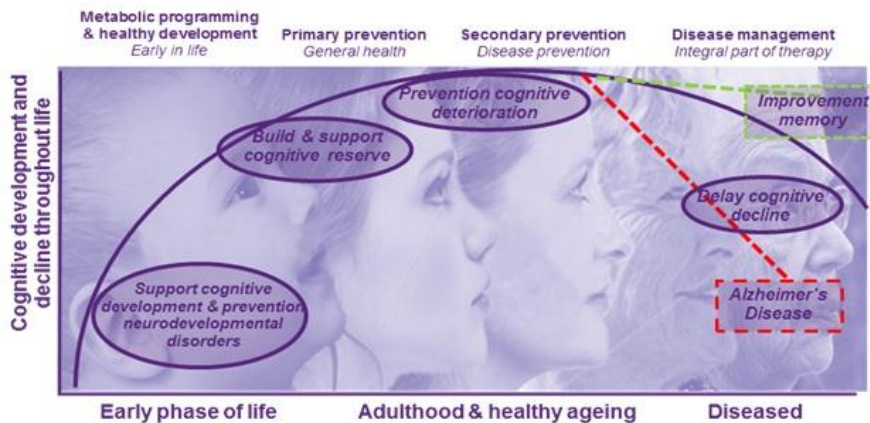
Increasingly, the Healthcare burden exerted by brain disorders is being understood. A recent study by the European College of Neuropsychopharmacology indicated that each year 38.2% of the EU population (168 million people) suffers from a brain disorder², with a cost burden of €798 billion in 2010³. A large proportion of this is due to neurodegenerative diseases (such as Alzheimer's disease) and stroke. These devastating conditions have an increasing prevalence in an ageing population, and are the most expensive from a healthcare perspective.



- In the US the annual cost of Alzheimer’s disease was estimated to be US\$184 billion in 2011; this is projected to rise to US\$1.1 trillion by 2050⁴ and a similar pattern of escalation is expected in Europe.

Currently limited disease-management or preventative therapies are available, for many diseases the available therapies provide only modest and temporary symptomatic relief. Specialised nutrition, through the translation of scientific insights into evidence-based practices, provides a powerful tool with which to mitigate the social suffering and healthcare burden imparted by these disorders.

Figure 1: Brain Health: Potential role of specialised nutrition in cognitive development and decline



3.3 EU Active and Healthy Ageing Initiative

In November 2011, the Steering Group of the pilot European Innovation Partnership on Active and Healthy Ageing decided upon joint actions in response to the societal challenge of an ageing European population. This Group, which comprised representatives from the health and social sectors, businesses, civil society and public authorities, agreed that the overriding objective was to ensure the average European citizen lived two more active and healthy years longer by 2020. This action plan is the first step towards that objective, and focuses on three main areas: prevention of disease, care and cure, and independent living.

Nutrition plays a central role in achieving these goals. Specific actions include:

- Co-operation to help prevent functional decline and frailty, with particular focus on malnutrition
- Development of innovative solutions to prevent falls and to support early diagnosis of diseases in the elderly
- The spread and promotion of successful and innovative integrated care models for chronic diseases among older patients via remote monitoring

3.4 EU Competitiveness²: Challenges and Opportunities

As research and innovation are key drivers of growth, increasing investment in Research & Development (R&D) is one of the five priorities of the Europe 2020 strategy. Total research investment in real terms rose by 50% in the EU between 1995 and 2008. However, as stated in Chapter 2, a rapidly growing share of total R&D activities is being carried out outside Europe.

Although Member States are introducing reforms to improve the functioning of the public research base and to increase public–private cooperation, knowledge transfer in Europe remains weak. The number of public–private joint publications per population in the EU is roughly half that of the US, and one-third lower than Japan. The opening up of research institutions and the development of a demand-led approach to innovation may help to address this deficit.

In a globalised economy, the competitive advantage of Europe lies mainly in its ability to compete on high-value-added products. However, Europe’s share in the world’s research capacity (investments and researchers) and output (publications and patents) is decreasing. In parallel with this long-term trend, major societal challenges, such as the ageing population, are creating new global needs and market opportunities. The EU, being the largest market in the world, should take full advantage of this by attracting investors to develop innovations that respond to the needs of consumers worldwide.

The EU food and nutrition industry has a strong heritage and is the largest manufacturing sector in Europe with a turnover of €965 billion in 2009. In order to secure growth and competitiveness in the European food sector, actions are required to stimulate knowledge-based focus and to increase the added value in technologies, products and services. With around 0.5% of turnover invested in R&D, the food sector in the EU is seriously lagging behind Japan and the United States. To increase added value will, in many cases, require that entrepreneurs, companies and investors be willing to collaborate across disciplinary boundaries and to take more risks in the R&D process. Collaboration between businesses and knowledge institutions can be fruitful in this development as long as the collaboration builds upon excellence in science, excellence in technologies and excellence in education.

The EC has recognized this and made food safety and security a priority theme in the Horizon 2020 program, which is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness⁴. The aim is to ensure substantial EU and national funding as well as private investment and partnering for bioeconomy research and innovation. Part of the action plan is to support bio-clusters knowledge and innovation communities (KICs) under the European Institute of Innovation and Technology (EIT) for partnering with the private sector. Other initiatives include the promotion of the FET flagship initiatives related to health such as the one on the future of medicine (ITFoM) focussing on metabolic diseases, or the Public Health Genomics European Network (PHGEN) giving guidance to the EU Member States in the field of public health.

The FOODBEST initiative is an international collaboration working towards a KIC in the food sector⁵. The project’s aim is to build the best European consortium in the food sector, which can be instrumental in bringing regional excellence centres closer together, thereby fostering a “best practice” and becoming the “frontrunners” for the rest of the European food sector. The EU’s strong heritage and position of the Food and Nutrition industry, combined with its advanced medical healthcare, skilled human resource, scientific excellence and size of its market, provide it with an excellent opportunity to create a unique competitive position in Integrated Healthcare.



3.5 Opportunities for Open Innovation in Nutrition & Healthcare

Innovation in healthcare currently focuses on patient care and disease mitigation. However, changing demographics, progress in medical science, major shortages of human and financial resources and empowered consumers have resulted in a paradigm shift towards prevention, participation and coaching⁶.

Further to this, an integrated approach is required that includes lifestyle and nutritional factors and calls for alignment between healthcare providers to integrate multiple healthcare solutions. To achieve this, a culture change in healthcare and close collaboration between healthcare, industry and regulatory stakeholders in an Open Innovation model is needed, delivering new business models.

Specialised nutrition has a key role in development, health maintenance and the prevention or delaying of disease onset or progression. In addition, the effective use of specialised nutrition, in combination with standard medical care, can also benefit patients' quality of life and survival. Integration of specialised nutrition in disease prevention and management strategies requires:

- Education on the role of nutrition in prevention, therapy and recovery to healthcare professionals and carers and on the availability of and access to specialised nutrition
- Determination of the processes underlying disease onset and progression. Such insights can lead to the development of novel biomarkers, risk factors and targets for early-stage nutritional intervention, enabling an integrated approach using nutrition, lifestyle and education to be initiated as soon as possible.

3.5.1 Example: Progressive Cognitive Decline

Progressive cognitive decline is typically associated with ageing, particularly in the case of Alzheimer's disease. Severe cognitive decline does not appear to be an inevitable process and is highly dependent on lifestyle factors, such as poor nutrition and physical inactivity^{7,8}. Epidemiological studies link specific nutritional deficiencies to cognitive impairment, and clinical studies have shown that targeting multiple nutritional aspects of the neurodegenerative process during the earliest possible phase is likely to have the greatest therapeutic potential (compared with single targeting)^{9,10}. New efforts are thus required to identify the multiple risk factors linked to cognitive decline, and to use these to develop targeted therapies.

These efforts include the creation of an Open Innovation network, enabling the translation of scientific insights into integrative care concepts by collaboration with:

- *Public knowledge institutes*: determine risk factor profiles for diet-, lifestyle- or metabolism-related conditions
- *Diagnostics companies*: develop easily accessible (point-of-care) devices that can reliably monitor these risk factors as part of a screening programme
- *Specialised nutrition and health and wellness companies*: develop integrated nutritional and lifestyle solutions to reduce the risk of developing disease, reduce or ameliorate complications, and improve treatment outcomes
- *Healthcare providers*: implement screening and nutritional and lifestyle intervention through (web-based) coaching and awareness programmes



This approach can also be applied to various other conditions, including muscle-degenerative conditions such as sarcopenia and cachexia, metabolic disorders (e.g. diabetes, obesity and related cardiovascular diseases) and allergic and respiratory diseases.

3.6 Barriers and Recommendations

Increase awareness of benefits of nutrition as integrated part of healthcare and stimulate implementation in practice

- Leverage European Innovation Partnership on Active and Healthy Ageing (EIP AHA): *‘Prevent functional decline and frailty, focus on malnutrition’*
- Improve the realisation of health-economic benefits through the application of nutrition as an integral part of healthcare. This should form part of European wide and member state level policy

Stimulate cross-discipline approaches to innovation in preventive health, combining early diagnosis, nutrition and therapies

- Study mechanism and course of disease throughout life and focus on early intervention and prevention
- Put the ‘patient’ at the centre of new, integrated healthcare approaches with focus on creating ‘patient value’

Ensure market access for evidence-based nutritional solutions to patients and consumers

- Maintain recognised regulatory space for Medical Nutrition (FSMP: ‘Food for Special Medical Purposes’)
- Evolve regulatory frameworks to allow nutritional solutions for early stage intervention as (secondary) prevention

Foods for Special Medical Purposes (FSMPs) are a special regulatory classification of foods under EU law that governs foods used for the dietary management of disease. FSMPs are used for patients who cannot consume regular foods or have special nutritional requirements because of their disease. As the products are used by people who have a disease, they are intended to be used under medical supervision. Importantly, FSMP products form an integral part of patient management, as their use is critical in improving patient outcomes. Use of FSMPs help to reduce the length of hospital stays, minimize re-admission and limit the need for other healthcare resources when prescribed and taken correctly. Further, use of FSMPs is consistently linked to lower mortality and complication rates for malnourished patients when compared to standard care. In many EU member states, the value of the FSMP category has been strongly supported with the application of reimbursement regulations allowing coverage by the National Health Systems. As reimbursement is linked to the specific category of FSMPs, it is critical that this category remains clearly defined and clearly differentiated from foods intended for normal consumption. Ensuring the safe and appropriate use of FSMPs is important to ensure the benefits of these products can be achieved. Thus, the ability to provide useful, factual information about FSMPs and their use to healthcare professionals is essential.

Our progressive understanding of biomarkers and diagnosis of early disease stages is changing the traditional distinction between ‘health’ and ‘disease’, into a continuum of disease predisposition, early pre-symptomatic physiological changes, first clinical manifestations and disease progression.



The advantage of early identification of disease biomarkers is that the efficacy (therapeutic window) can be larger in the early pre-symptomatic disease stages, and offer the greatest health potential for intervention with specialised nutrition. This needs to be addressed in future policymaking.

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Chapter 4

eHealth for Sustainable Healthcare

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4.1 eHealth for Sustainable Healthcare

Healthcare transformation, and in particular the need to implement eHealth capabilities to support new models of care, is being driven by many factors. As highlighted in other chapters, aging populations and the increasing prevalence of chronic diseases are placing higher demands on healthcare systems at a time when public sector budgets are being reduced. Across Europe, healthcare spend is on average almost 9% of GDP, a number expected to rise to approximately 16% by 2020. Coupled with a shortage of qualified personnel, European nations are facing increasing challenges in their ability to provide better-integrated and sustainable health and social services.

Enabling healthcare systems with new eHealth technologies can support different approaches, helping to increase efficiencies and productivity, improving quality and reducing per capita cost, and providing better access to services. Whilst significant progress has been made across Europe, much more needs to be done to fully realise the benefits of eHealth. Implementing eHealth is a journey that requires sustained effort as part of a broader healthcare transformation agenda, and needs to be managed as a complex change programme. At a time of austerity and pressured budgets, European Member States will be focusing on less complex, lower risk initiatives that deliver early value and returns.

The broad areas for focus and recommendations are: -

- Europe needs to increase research and innovation initiatives in the eHealth domain, particularly in the areas of usability, service science and the clinical pathway redesign which eHealth enables. These efforts should be interlinked, and should align with existing initiatives, such as the eHealth Governance Initiative and the eHealth Network. Benefits will



be realised by fostering an Open Innovation ecosystem that encourages large corporations, SMEs and academia to refine their roles within the innovation value chain, working within a robust and efficient IP protection system accessible to individuals and organisations of all sizes. The EU needs to accelerate its progress towards a harmonised EU-wide patent system that encourages faster value creation in support of healthcare transformation.

- Efforts to encourage the setting and use of open standards, such as the guidelines developed by the Calliope Thematic Network and the epSOS Large Scale Pilot, should be continued and further supported. The use of open standards is a critical ingredient in ensuring interoperability, and reducing the complexities associated with integrating disparate systems. Standardisation must include terminology, coding and semantic meaning so that healthcare information can be exchanged and understood consistently. This will speed adoption of the electronic health record (EHR), which is the cornerstone of a modern healthcare system. At the same time, the remaining complex legal, policy and regulatory challenges must be addressed if health information is to flow across national borders. Faster progress in these areas will inform and simplify national and cross-border eHealth initiatives to improve availability of EHRs to improve the quality of patient care.
- More effort is required to improve eHealth education and awareness across all domains – from physicians, to healthcare providers, to patients. In particular, the dialogue between clinicians and technologists about how eHealth can be used to improve medicine and healthcare must become more productive. The increasing expectations of citizens, influenced by experiences of other services, will facilitate consumer-led demand to transform health services to improve convenience, access and quality. Current efforts to share existing best practice and innovation that exist across Europe, such as the eHealth Network and the EIP on Active and Healthy Ageing, need to be built upon and extended further, to rapidly accelerate the diffusion of knowledge and innovation across Europe.

4.2 Introduction

In an era of rapidly aging populations and the corresponding need for management of chronic illnesses, heavy burdens are being placed on health systems around the world. The rising cost of healthcare is adding fuel to the transformation of the healthcare industry already underway. At the same time there is a fundamental shift in the expectations of all stakeholders – patients, governments, employers and healthcare providers. The ambitious plans of the UK Government to reform the NHS towards a patient-centred ‘no decision about me, without me’ model provides just one example¹. Yet the aim of being able to deliver the right care, to the right patients, at the right time is one that healthcare systems are struggling to achieve, despite increased healthcare spending.

Most nations and healthcare systems recognise that they cannot address these issues as they have in the past, though the challenges facing the healthcare industry are not unique. Other industries, such as financial services or consumer goods, have needed to innovate to expand both reach and quality of service while simultaneously reducing costs. These industries have sought to exploit digital information and technologies to achieve this, and it is this path that healthcare now needs to follow.

Technology can play a critical role in enabling healthcare transformation as clearly demonstrated by the FET flagship pilot project ITFoM on the future of medicine challenging “ICT for health” as well as “health for ICT. It can improve operations, support collaboration and lay the groundwork for data-driven decision making using in silico models (“virtual twins”). The ability to capture, integrate and analyse data across different stakeholders, care settings and geography is essential, as is modernising infrastructure to increase agility. New modalities, diagnostics and innovative medical devices, as well as the use of telemedicine and remote monitoring, add to technological enablement by increasing access and available expertise. Technology eliminates current service limitations by

overcoming barriers such as distance, knowledge or practice. It is a key enabler to transformation, and the healthcare industry must now utilise information technology for advantage, as so many other industries have, to innovate their businesses and to reduce disparities².

4.3 eHealth for Sustainable Healthcare

The term 'eHealth' is far from a new concept – the first prototype Electronic Healthcare Records (EHR) system was developed 50 years ago³ – however its definition can take on varied meanings. It has evolved over time, from the early introduction of information and communication technologies (ICT) into hospitals, primarily for administrative purposes and simple clinical record keeping, through to the technological underpinning of sophisticated telehealth systems. In this chapter eHealth is referred to in its broadest sense, as being the application of ICT across the whole range of functions that affect the health sector. It can include tools for health authorities and professionals as well as personalised health systems for patients and citizens. Examples include health information networks, electronic health records, telemedicine services, personal wearable and portable communicable systems, health portals, and many other information and communication technology-based tools assisting prevention, diagnosis, treatment, health monitoring, and lifestyle management.

The future sustainability of healthcare systems depends upon efforts made to provide efficient and affordable access to finite healthcare resources, with the aim of improving care for all and reducing healthcare inequalities. This is sometimes referred to as smarter healthcare. A smarter healthcare system can automatically capture accurate, real-time information, and is interconnected so that doctors, patients and administrators can all share information seamlessly and efficiently, and intelligent by applying advanced analytics to improve research, diagnosis and treatment. Implementing eHealth and smarter healthcare is a journey that orients people, processes and technologies around the patient for better outcomes.

Back in 2004, Europe set out its strategy towards eHealth⁴, with Member States now being at various points on the 'curve' towards smarter healthcare (Figure 4.1). There are a significant number of recent, on-going or planned initiatives including the implementation of Health Information Exchanges, ePrescription systems, Health Practitioner Portals, Citizen Portals and epSOS for the secure exchange of records between countries⁵. The promise of eHealth providing improved access to healthcare, whilst boosting the quality and effectiveness of services offered still resonates today, and continues to offer a potent means for health services in Europe and worldwide, to tackle the daunting challenges of the 21st century.

Progress towards adoption of eHealth across Europe remains steady, however it needs to be regarded as a complex journey as part of a broader healthcare transformation agenda. Implementation of eHealth capabilities can be time consuming, impacted by changes in stakeholders, policies and funding commitments, and that, if left unchecked, can lead to poorly integrated, disparate capabilities that fall short of realising the benefits that eHealth has to offer. Political will and continuity of purpose is an essential factor in delivering value from eHealth programmes.

Success will be driven by rigorous focus on the fundamentals of managing eHealth as part of a complex change programme that establishes a clear vision and strategy, and puts in place the appropriate governance and stakeholder management structures that allow component steps to be progressed towards the overall vision. Equally, new approaches and/or ways of working that drive innovation are needed.

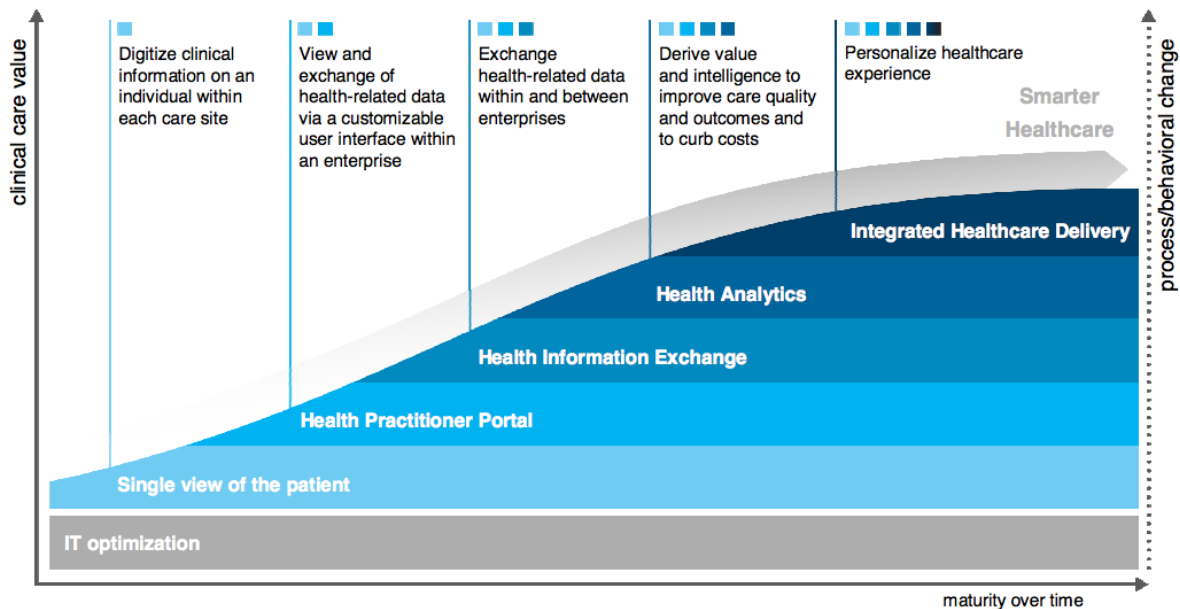


Figure 4.1 – Realising sustainable healthcare means orientating people, processes and technologies around the patient for better outcomes

The focus must be on healthcare information and patient data, facilitating its secure movement out of system silos and transforming it into intelligence for improved patient administration and enablement of patient-centred, coordinated care. Progress must continue, but in equal measure new ways of grasping the potential of rapidly emerging technologies must be sought, such as more integrated use of electronic health records (EHRs), greater sharing of digital communication between patients and physicians, and more prevalent use of technologies that drive remote diagnosis, treatment, care and patient education, with the objectives of achieving three critical aims:

- Increase citizen access and value
- Collaborate to improve quality, outcomes, and personalised care
- Build sustainable, cost effective healthcare systems

4.3.1 Increasing citizen access and value

People across Europe are enjoying longer life expectancies and healthier lifestyles than previous generations, however, inequalities in health still exist within and between Member States and regions. For instance, although the overall EU population is ageing, life expectancy at birth for women varies by 9 years between EU countries and for men by 13 years, and infant mortality rates vary six-fold⁶. Opportunities to both improve quality and expand access to healthcare within the same resources exist across all countries.

The challenges vary. For instance, in Norway where healthcare systems are generally considered to be amongst the most comprehensive, access challenges relate more to delivering care to citizens in remote regions. This will be increasingly seen in emerging economies, such as China and India, who have large populations spread over vast geographies.

Adopting new ways of accessing and improving the reach of health and social services is clearly important. Considering ways of evolving the quality and breadth of those services is equally necessary. Opening up new channels that, for example, allow patients to access their own healthcare information, potentially linked to personalised advice, will drive significant benefits. The ability to aggregate patient data to generate new insights into public health, or for epidemiological or medical research, represents a further source of value.

The World Health Organization (WHO) has previously identified inefficient and inequitable use of resources as among the three key impediments to universal access to healthcare, conservatively estimating that inefficiency wastes between 20 to 40 percent of all health spending⁷. Medicines account for three of the 10 most common causes of inefficiency. Reducing unnecessary expenditure on medicines and using them more appropriately, and improving quality control, could save countries up to 5 percent of their health expenditure. Among the other common sources of inefficiency are medical errors, such as incorrect or incomplete diagnosis, drug-to-drug interactions and similar adverse events. Getting care right the first time saves money and improves quality and outcomes. In order to increase citizen access and value, we will need to combine efforts that reduce process inefficiencies together with capturing value from enabling technologies.

4.3.2 Collaborating to improve quality and outcomes to deliver more personalised care

Use of information and communication technologies – including access to timely, comprehensive digital health information and medical records – enables a more collaborative approach to care that promises better results. Such is the case in Spain, where the regional health authority, Ib-Salud, launched its Balearic Telestroke programme in 2006. It used advanced video-imaging technologies, broadband networks and electronic health records (EHRs) to allow neurologists in the capital city, Palma, to provide time-sensitive, life saving stroke care across the remote islands in the Balearic archipelago. Patients who received telestroke treatment between July 2006 and November 2008 had three months post-stroke cure rates of 55 percent, comparable to the 59 percent cure rates for patients receiving face-to-face care⁹.

A further example can be found in Boston, where the Center for Connected Health operates programs for heart failure, hypertension, diabetes and other chronic illnesses. Connected Cardiac Care, a home telemonitoring and education program for heart failure patients at risk of hospitalisation, reduced readmission rate by nearly 50 percent¹⁰. Similar results are evident in its Diabetes Connect and Blood Pressure Connect self-management programmes that encourage patients to take a more proactive role in their own care. They typically yield better maintenance of treatment plans and healthier lifestyle choices.

Enabling a more collaborative approach requires getting the foundational capabilities in place. Consider the example of Cyprus, where efforts to implement an Integrated Healthcare System put Cyprus well on the path towards healthcare transformation. The Cyprus Ministry of Health initiated a large scale, transformation programme to automate its public hospitals. Benefits have been realised by taking the opportunity to reengineer, improve and homogenise healthcare services, leading to improved quality and efficiency whilst reducing cost as a consequence of increased control, reduced diagnostic tests and need for medicine prescriptions.

With the foundations in place, even more pronounced results are evident when empowering not just the patient, but the entire spectrum of practitioners involved in a patient's care, a practice known as coordinated care. Rather than focusing on single episodes of treatment, these 'care teams' take a more comprehensive approach, moving healthcare beyond a doctor's office or hospital and into the daily lives of patients. Such integrated care offers patients higher-quality, more efficient care that better meets their needs, often at a lower cost.

4.3.3 Build sustainable healthcare by reducing costs through analytics

Unlocking and harnessing the value of healthcare information is central to both improving the efficiency and the outcomes from healthcare delivery, and healthcare analytics could hold the key. At its core, eHealth represents an information management challenge, but one of tremendous scale and complexity. Vast volumes of integrated patient information generated by increasingly

instrumented and coordinated care teams can present challenges, particularly when medical insight is required in a timely manner.

Consider the case of the University of Ontario's Institute of Technology. The need was identified to better detect subtle warning signs of complications, to allow clinicians to gain greater insight into the moment-by-moment condition of patients¹¹. A special programme paired scientists with academic and healthcare professionals to explore how emerging technologies can solve these real-world problems. A first-of-its-kind, 'stream-computing' platform was developed to capture and analyse real-time data from medical monitors, alerting hospital staff to potential health problems before patients manifest clinical signs of infection or other issues. Early warning gives caregivers the ability to proactively deal with potential complications, such as detecting infections in premature infants up to 24 hours before they exhibit symptoms.

Increasingly, but not yet on a wide scale, standards-based medical networks are capable of capturing, storing, analysing, appropriately sharing and presenting information about individual patients and patient populations. For example, applying advanced analytics to help identify and compare individual patients with cohorts of similar cases could assist physicians in predicting future outcomes and deciding on a course of treatment.

The goal must be to use healthcare analytics to rapidly generate new clinical knowledge – maximising the use of existing clinical experiences and outcomes. Managing that knowledge and incorporating it into clinical processes and workflows is key, whether it involves patients communicating with their care delivery teams, collaboration among healthcare providers or medical researchers working across organisational, industry or country boundaries.

Emerging technologies such as cloud computing could help in this regard. Cloud computing can drive down costs, making administrative processes leaner and more efficient. For example, the Swedish Red Cross was able to save 20% of their IT operating costs when embracing the cloud, and increase collaboration and communications reliability, while freeing up to 25% of people's time to focus on more strategic tasks.¹²

4.4 Achievements and Successes in eHealth

eHealth has enjoyed significant focus and support across Europe, with steady progress being made. Whilst Member States are responsible for the delivery of health policy and provision of healthcare within their own boundaries, the European Commission's role is to act in the areas where Member States would find it difficult to act individually, or where cooperative action at the Community level is indispensable¹³. Focus at the EU level has therefore been on addressing the common challenges and creating the right framework to support eHealth, piloting initiatives to jumpstart eHealth delivery, and working to share best practices and measuring progress.

As part of the 2004 eHealth Action Plan, Member States were directed to put in place roadmaps for the adoption of eHealth together with monitoring plans to track progress⁴. A recent survey showed a dramatic increase in the number of country-based eHealth initiatives with a significant number of pilot evaluations underway⁵. Most focus has been on implementing Electronic Healthcare Record systems, telehealth and patient identification services, and understanding and addressing legal issues affecting the delivery of eHealth.

For example the Whole System Demonstrator was set up in the UK to provide a clear evidence base that supports the benefits of telehealth and telecare. The preliminary findings of this clinical trial suggest that telehealth can substantially reduce mortality, hospital admission rates, bed days spent

in hospital and time spent in A&E¹⁴. Similar examples of country-based, successful eHealth initiatives can be found across the Member States with varying degrees of maturity.

At the European-wide level, eHealth had also been selected as a lead market initiative as part of Europe's innovation agenda¹⁵, aimed at accelerating the development of the European eHealth market and highlighting the following as areas of intervention¹⁶:

- Reducing market fragmentation and lack of interoperability
- Improving legal certainty and citizen acceptance
- Facilitating access to funding through increased visibility
- Improving procurement through more innovation-friendly procurement activities

The innovation agenda reported partial success, mainly around improving interoperability through new directives and the outcomes of the eSOS pilot¹⁷. Interventions to address legal certainties, citizen acceptance and innovative funding approaches need further effort. A number of the goals of the Digital Agenda for Europe (published in 2010) concern online patient access to health records and widespread adoption of telemedicine by 2020, and several recent EU initiatives aim to further these goals, including the EIP on Active and Health Ageing, and the establishment of the eHealth Network.

4.5 Barriers to eHealth Adoption

In December 2009, the Member States adopted the Council Conclusions on Safe and efficient healthcare through eHealth¹⁸, agreeing to the need for updating the eHealth Action Plan published in 2004. Closing in May 2011, a mandatory public consultation exercise was undertaken to validate the following proposed future objectives for eHealth¹⁹:

- Increasing awareness of the benefits and opportunities of eHealth, and empowering citizens, patients and healthcare professionals
- Address issues currently impeding eHealth interoperability
- Improve legal certainty for eHealth and health data so it can flow over borders seamlessly
- Support research and innovation in eHealth and development of a competitive European market

In responding to the consultation, barriers impeding the deployment of eHealth and that the European Commission should address, were also identified:

- The need to support systematic evaluation of the benefits versus costs and risks, effectiveness/usefulness of eHealth solutions
- Improving interoperability and strengthening the evidence-based approach
- Accelerating the Digital Single Market
- Facilitating cooperation between Member States and regions, and exploring innovative financing and reimbursement schemes.

In addition to the above, whilst the current model in which Member States are responsible for driving their own eHealth implementations is the right one, it is open to inefficiencies as economies of scale can be missed. eHealth implementations by their nature are complex programmes that have a high degree of ICT requirements, which industry statistics would show are most likely to suffer delays and budget overrun issues. As such, they need to be managed as part of a complex change programme with a clear vision and strategy, together with supporting governance and stakeholder management capabilities. Strong sharing of best practices is also a key ingredient.



eHealth is entering a new period as stated in the eHealth Task Force report of the European Union entitled “Redesigning health in Europe for 2020”. With objectives broadly validated, a voluntary eHealth Network has been set up with representatives from all Member States, as well as an eHealth Stakeholder Group comprising industry and user groups. These two bodies will advise on eHealth policy and the role of ICT and will shape the delivery of the eHealth Action Plan 2012-2020²⁰. It will seek to improve education, training and visibility, address legal and liability concerns, consider the need for policy or regulatory changes, and make investments that provide a clear evidence base for further adoption of eHealth. The eHealth Action Plan 2012-2020 is expected to be published in the next few months.

The timing is precisely right, therefore, to consider how adopting a more Open Innovation approach to eHealth efforts can help accelerate current progress.

4.6 Opportunities for Open Innovation in eHealth

Open Innovation is gaining increasing focus, particularly within large organisations but also by SMEs and across academia. It presents a paradigm where organisations can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their products or technologies²¹. Its origins have tended to be focused on product innovation, highly applicable to the manufacturing sector, however it also lends value to the services sector that equally depends on innovation. Indeed, much research has placed emphasis on the intersection between Open Innovation and services science, with a renewed focus on open services innovation²².

Organisations are increasingly looking beyond traditional R&D for sources of innovation and new ideas²³ as described in chapter 2. To adopt an open or closed innovation process is not a binary decision, rather organisations will seek to adopt approaches that position where they want to play within the innovation value chain. However, the challenges of the coming decades mean that industry, government and academia will need to more openly collaborate to expedite innovative solutions. Open Innovation requires IP to be regarded and managed in new ways, such that maximum opportunity is provided for others to build on resulting outcomes. It can be interpreted that Open Innovation requires a less regimented approach to IP management, but rather the reverse is true. A robust approach to managing IP is needed, such that required protections are in place and that the licensing and/or transfer of technologies can be facilitated in a much more efficient manner.

The applicability of Open Innovation to healthcare is perhaps less apparent than to other industries that have maintained more traditional R&D approaches, such as in pharmaceuticals. However, there are clear steps that Europe can take to foster an innovation environment that better supports Open Innovation to drive increased value in healthcare.

Consider the example of self-monitoring of blood glucose (SMBG), now recognised as an important component of managing diabetes. There are a plethora of blood glucose meters of varying forms and functions. Yet, there are few examples that allow a patient’s data captured at home to be uploaded for proactive review by their healthcare teams. In an increasingly consumer-led technological world, with high adoption rates of smartphones and similar devices, it might be expected that a range of glucometers of this nature would be available. Each able to interoperate with different smartphone platforms via standards-based message formats and protocols, as an example. This appears to be less the case. Even the underlying method for measuring blood glucose has remained largely static, requiring regular pinpricks of blood that does little to improve quality of life for diabetes sufferers. Is enough being done to innovate new approaches that would have a positive impact on diabetes sufferers across Europe, and wider?



This is just one area where the EU can do more to ensure the right policies are in place to enable an Open Innovation ecosystem to emerge. Much work is being done in Europe and worldwide on standards for medical devices. Efforts need to be maintained; particularly with setting open standards for how data is captured and communicated. A flourishing innovation ecosystem would see an external explosion of new players emerging, creating value by manipulating this data in new and unforeseen ways. But for this to happen requires more than just the setting of open standards and interoperability.

Uncertainties remain in how data of this nature should be regarded, and the security and privacy requirements entailed. For example, in pseudo-anonymised form, does this require the full data protection of sensitive patient data? Where are the boundaries crossed, particularly as more telehealth and telecare implementations that seek to provide home monitoring of blood pressure, movement and similar exist?

Legal and liability concerns are a further area where the EU can drive progress. In a remotely accessible monitoring service of this nature, there would likely be many participants involved. From the medical device manufacturer, to the network connectivity provider, to the application provider that surfaces the content, to the decision support system that alerts when a threshold has been reached. What happens in the circumstances where the device submits false readings that remain unchecked for several weeks and ends with a patient requiring chronic care? Where does the liability reside? For sure, the medical device manufacturer can remove single points of failure, and can strengthen the individual service component. But what happens in the spaces between service components – for example, should the ‘appstore’ provider assume liability for not certifying the application correctly? Which components in the chain need to be classified as regulated medical devices rather than consumer products?

Increasing awareness of the benefits and opportunities of eHealth is critically important. Healthcare professionals are sometimes reticent to adopt new technologies because of complicated user experiences and additional workload with no clear and measurable value, lack of transparency about cost and ongoing privacy concerns. In adopting technology, the users experience must be substantially improved without putting additional burdens on healthcare professionals. Open Innovation requires that users are more fully involved in the innovation process, co-creating new products and services. It will be the resulting pull from citizens asking for these technology-enabled services that will build the momentum for change.

Building more open, interoperable and robust health information technology environments is the key to expanding access, improving care and reducing healthcare costs, and efforts to address interoperability via an open standards based approach must be maintained. The EU should create the right policies that accelerate the adoption of open standards, but to also seed the right investments to create the demonstrator or pilot systems that drive adoption and allow external parties to see the value being created that can be built upon. We need to make more openly visible the benefits and fruits of progress – not just to those who are direct consumers today, but to those ‘unknowns’ who can apply new thinking and approaches, and move the cycle forward.

More needs to be done to explore innovative funding models, both at the EU and regional levels. The value of health information locked in system silos today needs to be better understood, and how this can be made available, with the right security and privacy controls, in order to create new marketplaces that stimulate further investment and innovation. The EU needs to act as the catalyst, creating the conditions for Open Innovation to occur and that allows platforms to emerge for others to build upon and create new value.



eHealth initiatives must be proactively funded, potentially in favour of other initiatives. They must be selected based on their furtherance of wider EU goals – through funding basic research, to implementing critical pilots – where success will inform the greater ecosystem and not simply deliver a point capability. Open Innovation will drive participation of many more individuals and organisations in the marketplace. It will make for a more prosperous Europe, sharing the risks and rewards of innovation, bringing down its costs and accelerating the speed with which innovations can be brought to bear.

4.7 Recommendations

Successfully implementing eHealth programmes to enable healthcare transformation is complex, even though many of the technical challenges have been solved. For many countries across Europe, the biggest hurdles to success include other factors such as governance, policy and legal concerns. Healthcare transformation is a journey that can take many years of sustained effort, requiring effective change management and governance processes. The EU should encourage Member States to maintain a clear vision of the future of their healthcare systems, and to ensure that the appropriate governance bodies and models are established to drive the implementation of building block solutions, standards, incentives and payment models that will see delivery of key component parts that work and interoperate together at a national level. . At the same time, the EU should build on the work already done to guide Member States such as provided by the DG SANCO supported Public Health Genomics European Network (PHGEN, www.phgen.eu) or by highly innovative and even disruptive initiatives such as the EU FET flagship project ITFoM on the future of medicine (www.itfom.eu).

With a key driver being able to more effectively serve constituents with existing or even fewer resources, an important element is the implementation of new clinical pathways supported by eHealth technologies that provide access to real-time healthcare information. This will require more effort in the areas of usability, service science and the clinical pathway redesign which eHealth enables. These efforts should be interlinked, and should align with existing initiatives, such as the eHealth Governance Initiative and the eHealth Network.

However, in the face of shrinking budgets, most Member States will want to avoid implementing comprehensive national eHealth systems. Instead, they will choose to begin their journey with eHealth solutions that can be deployed quickly, at lower complexity and risk, and that deliver immediate value for their investment. Implementation of fully interoperable EHRs that are accessible by all care providers and patients, potentially across borders, will perhaps remain a longer-term goal rather than offer a first step towards healthcare transformation.

Of the challenges and barriers to eHealth identified as part of the recent EU study, increasing awareness of the benefits and opportunities of eHealth, and empowering citizens, patients and healthcare professionals is a key one. Much work is already underway to support end-user education and knowledge sharing. For example, stakeholder advisory groups exist, as well as online portals where case studies and best practices can be shared. These efforts need to continue and be built upon, perhaps with greater use of social media, including crowd sourcing and social media analytics, to drive the further diffusion of innovation and best practice. In addition, the dialogue between clinicians and technologists needs to become more productive, if the full value of eHealth is to be delivered.

A specific area where the EU can take a more energetic role is to encourage Member States to pursue public health improvement initiatives that help individuals proactively manage their own health and wellness more effectively. Citizens that are better able to educate themselves will be empowered to manage their own conditions, enabling a different dialogue with their physicians to

improve care and reduce burden. Promoting eHealth systems that maintain such services, including greater usage of health social networks that allow citizens to exchange thoughts and experiences, will increasingly empower patients without reducing the valuable role of healthcare professionals. It will drive a patient-centred approach that will additionally see citizens play a more proactive role in the specification and delivery of new healthcare services. Open Innovation warrants that user suggestions, such as from patients or providers, are actively sought to inform and drive better healthcare service delivery.

Much work is already underway to address issues currently impeding eHealth interoperability, as this has been one of the main focus areas of the EU through initiatives such as epSOS that includes, for example, the ability to transfer ePrescriptions and Summary Care Records across national borders as one of its goals. The EU should continue to strongly support the adoption of international open standards, to drive interoperability and open up fair competition within the marketplace. In particular, the EU should proactively target investment funding to programmes of activity that move open standards into deployed demonstrators to drive adoption.

Improving legal certainty for eHealth remains a key challenge, requiring further assessment of where issues lie across the domains of data privacy and protection, and liability concerns. The barriers of entry, particularly to SMEs, need to be reduced, to enable a level playing field with large organisations and other institutions that enjoy greater access to resources that enable them to better understand and address these challenges.

It is in the area of supporting research and innovation in eHealth and development of a competitive European marketplace where fostering an Open Innovation environment is most important. Europe needs to consider how it improves the breadth and quality of innovation, both to drive improvements and successes in eHealth but also to contribute to the economic value in Europe through development of a more competitive European marketplace. The innovation value chain flows from the creation of knowledge, through its development and onto its eventual commercialisation and return. Europe needs to make a conscious decision as to which part, or parts, of the innovation value chain it wishes to focus its efforts. In a world economy, Europe may choose to become the hotbed for innovation incubation, but be comfortable perhaps that commercialisation is undertaken elsewhere. There is not necessarily a right or wrong approach, however maintaining a clear view will allow the appropriate policies and incentives to emerge that support the intended outcome.

All too often knowledge generated within an organisation or institution may be withheld, even when it is clear, there is no intention for the organisation to seek to commercialise its future value. Open Innovation requires a different approach to the management of IP, where IP becomes regarded as a currency, easily traded or exchanged. In likelihood, there may be knowledge withheld by institutions today that could generate significant value if recombined by others to address different challenges. The starting point needs to be the ease with which IP protection can be assured, such that organisations are encouraged to find new opportunities for applying their ideas. Equally, a culture needs to be established where organisations see value in proactively looking at new ways to commercialise ideas that are not core to their own business, but could be used to tackle complex challenges in healthcare.

In this regard, the current IP systems in place across Europe are sub-optimal. It is more complex and costly to patent ideas and technologies in Europe, in part due to the need for replication in each Member State. It takes longer to achieve protection than in other global economies, such as the US. Efforts to move towards a harmonised EU-wide patent system need to be accelerated, to reduce the



time and cost of achieving IP protection, allowing for easy and cost effective access to individuals and organisations of all sizes.

Benefits will be realised by fostering an Open Innovation ecosystem that encourages large corporations, SMEs and academia to review and refocus their roles within the innovation value chain. Open Innovation will stem from increased collaboration between organisations of all sizes, identifying, developing and commercialising innovative approaches for addressing real healthcare challenges. This will stimulate the emergence of intermediaries to act as knowledge brokers, bringing together large organisations, SMEs and academia at the point of need. The EU should consider how it can direct Member States to encourage and incentivise the emergence of these knowledge intermediaries.

Efforts to encourage the setting and use of open standards should be continued and further supported. The use of open standards is a critical ingredient in levelling the playing field such that organisations, both small and large, can compete effectively. Further, the use of open standards is a key building block in ensuring interoperability, and reducing the complexities associated with integrating disparate systems.

Funding models that better support start-ups need to be explored, not to replace existing models in place today, such as venture capital funding, but to supplement it such that capabilities can mature within the EU rather than forced to a timeline dictated by venture capitalists demanding a fast return on their investment.

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Chapter 5

Towards Personalised Medicine

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5.1 Towards Personalised Medicine

This chapter makes the case for the critical importance of a personalised healthcare and medicine strategy for the future sustainability of the EU economy – one where Open Innovation offers real opportunity for progress and impact. Industry and society need to agree the priorities which reflect the highest unmet needs and where society expects the biotechnology, pharmaceutical and diagnostic industries to focus. Much is already being done at a EU level, for example the EAPM stakeholder engagement model offers the opportunity for greater support from citizens and a cross-section of stakeholders. And this and other initiatives should facilitate the development of an overall healthcare financing strategy to address these challenges; especially through mechanisms of shared risks and benefits such as the reinvestment of profits to speed R&D in (or delivery of treatments for) diseases of particular regional interest. These priorities would also benefit from endorsement by regulatory bodies, payers and healthcare providers to ensure that innovation is appropriately recognised and rewarded.

Cutting across individual therapeutic priorities is the imperative for adopting a personalised medicine agenda, which can utilise an Open Innovation framework to drive new ways of working within and across sectors. Here the EAPM definition of personalised medicine is used i.e. "a targeted approach to the prevention, diagnosis and treatment of disease based on an individual's specific profile. The adoption of a personalised medicine agenda does not exclude the use of a population-based health agenda for medicines, and vaccines, but fills a need where such a population-based approach is inappropriate or inefficient. The ultimate aim of both approaches is to generate the



maximum benefit whilst reducing risk, and cost, through creating the optimal patient/population treatment match.

The following summary recommendations are made to support the development of personalised healthcare research in the EU:

- Increased support for partnerships and innovative models of collaboration, especially in the area of Therapeutic-Diagnostic-Biotechnology-Academic partnerships, to identify and mature technologies and products. This will include driving cost & benefit sharing models between industries, healthcare providers and payers, covering IP management, commercialisation and R&D investment
- Introduction and adoption of policies and strategies that will accelerate the adoption of the realisation of the benefits of a personalised medicine approach to healthcare. This will include the development of policies and rapid regulatory and reimbursement processes for novel, high value therapeutics and vaccines including those requiring companion technologies like diagnostic assays. The European Best Practise Guidelines developed by PHGEN and endorsed by the EU Member States can serve as a guidance for the next years in that field (www.phgen.eu)
- Improvement of the IP environment within Europe through both the enhancement of e-training of technology transfer officers, IP attorneys and others to stimulate new ways of IP transactions and publicise best practice examples to accelerate the adoption of a single EU patent system
- Focus on the development of education and communication initiatives and the concept of health literacy to position 'Personalised Medicine' in the lexicon of healthcare provision, including education of patients and healthcare professionals as promoted by the EAPM

5.2 Introduction

The EU faces many major healthcare challenges with a trend for the burden of chronic diseases to increase, especially in an ageing population where prevention or early intervention could have a major impact (See Chapter 2: Background).

However, current healthcare systems and processes are more orientated to provide acute, reactive, care rather than on treating and modifying the progression of these chronic conditions or their prevention. There appears to be little accountability for the holistic "cost of the patient" due to the increasing fragmentation in financing and delivery of healthcare across the EU. With funding for medicines, vaccines, diagnostics and other interventions being held in separate envelopes or even being managed by separate entities, rewarding innovation based on integrated solutions is currently very limited, yet this is the cornerstone of 'Personalised Medicine'.

The current economic environment has further focussed national healthcare funders on short-term cost savings. Personalised medicine allows for the identification of the optimum treatment for a patient based on knowledge specific to them (e.g. biomarkers, disease history etc.). It is distinct from stratified medicine where patients are grouped ('stratified') into particular categories based on biomarkers and other indices, like age. Whether a population has a stratified or personalised healthcare solution delivered will depend in part on the disease and the state of knowledge of the relevant bioscience. However, the current healthcare systems within Europe are not conducive to these types of innovation and are leading to a situation where the EU only takes up mature innovations once they have been developed and commercialised elsewhere.

In terms of pharmaceutical R&D, the previously closed innovation model of R&D has resulted in duplication with companies and institutions pursuing the same targets in parallel and not sharing the results of successful or failed studies. This too adds to the overall cost of delivering innovation, and will ultimately delay access to those who need these innovations most.

Yet, there are significant opportunities which, given the right environment and incentives for innovation, could create economic value for Europe not just through more effective healthcare delivery but also through the expansion of the industrial and academic base underpinning healthcare. The pharmaceutical industry still directly employs over 640,000 people, 115,000 of which are involved in R&D (EFPIA Pharmaceutical Industry in Figures 2011) providing an excellent basis for innovation driven expansion.

By adopting an Open Innovation strategy, the EU could lead the world in cost effective healthcare whilst maintaining or even increasing quality at all points along the value chain. For example coronary angioplasty was invented in tertiary care centres by experts, but is more cost effectively done in dedicated clinics focussing on a narrow range of procedures. In this setting quality and speed increased, service improved (better accommodation and nursing care) and costs decreased but a fundamental shift in the way the healthcare solution was delivered was needed. There was an increased focus on the “full cost of the patient” with clear accountability, and a long-term strategy that was essential in enabling the change in thinking required to deliver the new model of working.

Changes in the way patients are viewed are already being employed in some areas. For example, a stratified medicine approach where patients are stratified into groups on the basis of response is used in deciding on the most appropriate individual cancer therapy. Personalised medicines and healthcare technologies, which can be designed for patients on the basis of a specific biomarker or profile, are now feasible in many therapeutic areas but there are challenges to their implementation e.g. current regulatory frameworks and lack of incentives for uptake of personalised medicine.

The segmentation of patient population pools relative to those available today will mean that coordination across the EU healthcare systems will be essential. This will ensure that sufficient patient numbers with the relevant profiles are available for clinical trials so that suitable candidates across countries can be invited to participate in studies. A number of eHealth initiatives that will address this issue are already underway within Europe and further initiatives planned (see Chapter 4). However, a failure to implement such systems will lead to delays in subject recruitment, lack of access to studies and thus delays in the development and registration of these innovative medicines and vaccines across Europe, especially relative to the United States of America (USA).

Alongside this more personalised approach, much publically funded healthcare can be considered ‘population’ healthcare, where standard medicines, vaccines and interventions are deployed across vast segments of society. In the transition to personalised medicines, healthcare funders, providers and the population as a whole will need to ascribe to policies that aim to provide the most appropriate medicine, vaccine or intervention for each individual. This in turn will require the development of accompanying regulatory and reimbursement, or other funding, frameworks to accommodate coverage of certain innovations for certain patients and others for others. It will also require consideration of how ‘subsequent in class’ innovations will be handled as higher hurdle rates than the ‘first in class’ entrants may lead to a stifling of innovation.

The EU will need to find ways to embrace these and other technological advances and furthermore to create an environment where they can be optimally deployed. A failure to do this could lead to a situation where the EU is not seen as the place to develop healthcare innovations nor as a place to deploy or access innovations. In countries like the USA, companies can get development capital

more easily and are reimbursed as soon as they launch a product. Europe's conservative practices and difficult reimbursement hurdles encourages companies to develop new therapies in markets with large populations, increasingly well-developed healthcare systems, less conservative attitudes and easier reimbursement systems (e.g. Brazil, Russia, India, China) as is already the case for Phase III clinical trials (see Chapter 2). The following sections highlight key areas where strategically driven policy and other changes at a EU level could enable Open Innovation to deliver value for healthcare and enhance the EU's competitiveness.

5.3 Partnerships and Innovative Collaborative Models

Partnerships and collaboration are key to Open Innovation. For Europe to address the key societal challenges that have been identified in Horizon 2020 and ensure that excellence in science and innovation are supported to safeguard its international competitiveness there needs to be an increased focus on partnerships, particularly public private partnerships (PPPs). This would work to boost the EU's science base and support industrial competitiveness, via cross-border pooling of resources and experience. It would also assist in achieving the necessary critical mass and diffusion of knowledge, across multiple stakeholders leading to and promoting increasing levels of excellence in R&D. The willingness of large companies to outsource significant portions of their early R&D brings significant opportunities. To realise these, it will be essential that Europe's scientific society (academia, SMEs), industry) come together to tackle key scientific and commercial issues.

Such PPPs will be able to exploit new mechanisms and financial instruments to enhance innovation along the whole value chain from early R&D to manufacturing. At the early R&D end of the spectrum, Governments and other science funding organisations have substantially increased healthcare research funding to facilitate access to both data and screening facilities. Examples of such investment include the National Institutes of Health (NIH) molecule libraries initiative, PubChem and the Wellcome Trust funded ChEMBL database. The increased focus on good public domain data and resources, combined with the increased movement of staff from industry to the public domain may offer an important opportunity to further improve partnership between public and private sectors. This is also being reflected by the announcement of major open access drug discovery projects, such as The Archipelago To Proof Of Concept in Medicine (Arch2POCM), which aims to use a crowd-sourcing approach to take small molecules for autism, schizophrenia and cancer into man.

The EU should consider how to best facilitate the types of data sharing that underpins such projects and build on the success of the Innovative Medicines Initiative (IMI) and other initiatives funded under the Framework, and other, programmes. Specifically, this could focus on the way in which these newly created resources can be accessed and used both within and across specific sectors to stimulate innovation in healthcare. More generally, consideration is needed of how to stimulate further collaboration, which could accelerate the application of current and future projects, such as IMI, to the patient.

There is also a need for Europe's scientific society to recognise the increasingly international nature of research and seek synergies with international research initiatives. The EU has much to offer, and to benefit from, such increased international collaboration, given the current debate on the global nature of public healthcare needs. A pan-European and ideally global approach is required to support the identification of new drug-able targets, optimize treatment paradigms and develop preventative strategies within this framework. Such an approach will rely heavily on collaboration and sharing of information.

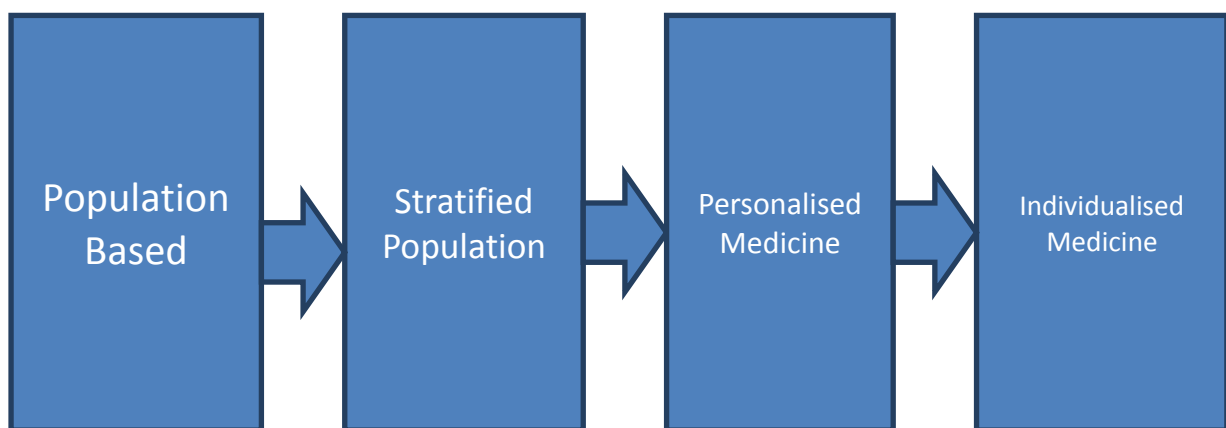
It is recommended that the EU should seek to further enhance PPPs; especially in the area of Therapeutic-Diagnostic-Biotechnology and Academic partnerships.



There are many ways this might be achieved e.g.:-

- Streamline, coordinate and enable cross-fertilisation between schemes & programmes; especially to facilitate the interaction of sectors that have previously been silos
- Take partnerships that have already been funded to next stage of implementation
- Dramatically reducing the administrative complexity of EU funded PPP initiatives and ensuring best practice for governance is implemented e.g. clear timelines, deliverables and milestones
- Encouraging synergies with national / international innovation-oriented programmes; stimulating participation of industries and academic centres of excellence from other geographies in areas of strategic relevance to the EU
- Finding further ways of using innovative collaborative models to address barriers in accelerating approval on biomarkers for safety and efficacy especially through creation of incentives at the reimbursement level

5.4 - Developing a Personalised Medicines Agenda



There is no doubt that the development of personalised medicine will be critical for progress in new therapeutics both in terms of treatment and prevention. However, there is a need to better educate all stakeholders of the benefits of this approach. Much of the current infrastructure both in terms of basic R&D, as well as clinical practice, is not aligned to this new vision and remains focused on a population-based approach. Future clinical practice will require more rapid adjustment of diagnostic and treatment patient algorithms. For example, in oncology traditionally mostly computerised tomography (CT) scans and pathology are used in diagnosis and therapy follow-up whereas today there are more advanced technologies from imaging (positron emission tomography (PET) & magnetic resonance imaging (MRI)) and other biomarkers which can provide additional biochemical or physiological information. However, the uptake of these in clinical practice has been slow. There is a real need to influence and educate clinicians to drive more rapid adoption of technologies for patient benefit. Increasing the role of patient advocacy groups in driving this change should also be incentivised.

There are also opportunities for improvement of the regulatory framework to make it more fit for purpose in an era of both population-based and personalised medicine. There is a lack of integration in terms of approval mechanisms for the development of companion diagnostics and devices to enable a truly personalised medicine approach. Better integration at the level of regulatory approval would position the EU well for the development of individualised medicines. This will be essential in order to capitalise on any improvements in clinical surrogate endpoints in terms of personalised outcomes in prevention and treatment of chronic disease (e.g. neurodegeneration, cardiovascular disease). New endpoints will be required if the advantages of preventative therapies are to be demonstrated cost effectively. Such innovative diagnostics, or surrogate markers, need to be



developed in a simplified and expedited manner in order to be incorporated into therapeutic programmes in a timely manner.

5.4.1. Increasing the Impact of New Technologies

As mentioned above, there have been tremendous advances including the development of genomics, proteomics and metabolomics, which are providing insights into disease mechanisms and patient heterogeneity. The molecular basis of diseases such as cancer is becoming better understood, as stated and proved by IMI cancer initiatives such as OncoTrack although significant challenges remain in areas such as central nervous system (CNS) disorders. In these areas, genetics is suggesting that a new taxonomy of disease (pathway-driven) may be required to maximise the similarities across conditions, rather than focusing on their differentiating features. Stratification by mechanism, rather than disease, may offer new opportunities to accelerate the translation of early research findings into effective therapeutics by combining data from patients with different disease phenotypes underpinned by the same mechanism (e.g. specific immuno-modulatory approaches in subsets of Multiple Sclerosis, Inflammatory Bowel Disease and Rheumatoid Arthritis patients), prevalence of common biomarkers and driving mutations across multiple cancer types. This will need a radically new mindset not only from the industrial perspective but also from regulators and payers. Personalised medicine will require greater in depth knowledge of disease pathways and molecular targets which could exploit the strong academic and commercial base in terms of biomarker identification and early development within the EU. It will also require a pool of talent in both basic science and its translation to products.

The opportunities provided by the development of stem cell technologies will also be important for developing a personalised medicine agenda. Although beyond the scope of this review, it is recommended that these developments be closely monitored so that the EU can provide the appropriate environment to ensure rapid implementation and uptake of the benefits these advances could bring.

Incentives will also be required for standardisation, as this will drive the use of new technologies and data. In terms of personalised medicine, technologies such as next generation sequencing (EU <http://eurogentest.org/>) that will significantly reduce the cost of accessing an individual's complete genomic information, digital pathology (next generation immunohistochemistry), multiplexing technology, mobile applications for health, e-health and imaging technologies could have enormous impact. There are both challenges but also opportunities in the standardisation of processes both within and across countries in the EU, with the aim of enabling new technologies to emerge quickly, be more thoroughly assessed in early use and integrate as seamlessly as possible with existing technology and data. This will allow the EU to capitalise on programmes and Joint Technology Initiatives that have been funded under the Framework 7 programme such as the IMI and in other areas such as nanomedicine.

How these large bodies of personal data are accessed, protected and used to accelerate a personalised medicine strategy will also bring challenges. The enhanced translation of these diverse and complex research data through integration towards clinically relevant use needs, not only standardisation of existing frameworks, but also the establishment of new methods of integration. This is an area where the EU could build on experience in sectors outside healthcare (e.g. semiconductors) and incentivise precompetitive collaboration and standardisation through either financial or regulatory means. In addition, health systems will need to coordinate at both a national and regional level to access these smaller and smaller patient groups for clinical trials.



5.4.2. Exploiting New Trial Methodologies

New clinical trial methodologies need to be more widely adopted and recognised. This would facilitate a move away from the traditional phases of drug development and would enable R&D to be conducted in a more efficient, cost-effective manner by applying effective decision-making and novel tools to minimise attrition during later phases of clinical/confirmatory development. The half century old randomised control clinical trial has been the yardstick of clinical trial design, yet whilst science, medicine and technologies have advanced dramatically during this period, R&D and the associated regulatory processes have remained largely the same and thus this unchanged framework has become steadily onerous.

There needs to be greater acceptance of new techniques such as modelling and simulation techniques, Bayesian methodologies and adaptive designs for clinical trials (e.g. seamless adaptive designs methods) require wider adoption and recognition. Key to this increased recognition is the demonstration of how biological, pharmacological and statistical modelling synergies can be better utilised throughout the drug development process to maximise their potential impact and demonstrate the benefits of such approaches. The use of such approaches would also provide societal benefit as, using the methodological technological advances described above, only those patients more likely to benefit from the therapeutic agent in question will be included in a particular trial. Such an understanding of the benefit/risk ratio would thus reduce inappropriate exposure of patients to a treatment, which might be ineffective or poorly tolerated by them.

New trial methodologies should also be expanded into more naturalistic approaches such as other healthcare interventions e.g. diet and lifestyle. In addition, the implications of the use of social networking within patient communities for clinical trials need to be more fully understood (e.g. PatientsLikeMe). The engagement of regulators and patient advocacy groups, such as the newly formed EAPM, will be critical to identifying viable approaches both in terms of funding opportunities, training and incentives.

There are precedents for adopting new regulatory frameworks need to be explored for personalised therapies. For example, R&D of new medicines for orphan diseases was incentivised by making the route to filing more cost and time efficient. For pandemic vaccines, the EMA established an *a priori* filing mechanism based on a 'mock up' file years in advance of the 2009/10 H1N1 pandemic which greatly reduced the access time for these critical vaccines down to just 6 months at a time when they were most needed. Similar ways to encourage the development of personalised therapies should be considered.

5.4.3. Key Benefits of Personalised Medicine Approach to Healthcare Innovation

The use of personalised medicine should lead to enhanced benefits for the patient and the payer and bring increased value to the healthcare sector through improved efficacy and safety. As mentioned above, medicines currently prescribed are not equally efficacious in all patients and therefore there are some patients for who the risk benefit ratio may not be optimal. In addition, targeting medicines to those patients who are likely to derive the most benefit might enable better dosage optimisation and may also increase compliance.

In the area of oncology these benefits are already being recognised. One of the most notable drugs is Herceptin, which is used based on 'HER2 testing'. HER2 testing is performed on tumour tissue, and aims to measure whether the tumour is over expressing a receptor called HER2. If so, the patient is much more likely to respond to Herceptin and the patient is considered for treatment. In 2012 many, if not most, of the cancer drugs in development have parallel programs to identify biomarkers, like HER2, which might be used to predict which patients are most likely to respond positively to the drugs. Indeed this success has spurred many companies to develop products and



services in the oncology area e.g. tests, which utilise information from the expression of multiple genes in a tumour, to help decide which breast cancer patients should receive adjuvant chemotherapy and, just as importantly, which patients should not. Such biomarker testing services aim to help physicians choose between available therapies, based on the biomarkers expressed in a patient's tumour. Clearly this approach should be much more effective and cost efficient, which is in the interests of both the healthcare provider and the patient. Lessons learned from these efforts in oncology, both positive and negative, could inform other therapeutic areas.

It is recommended that the EU should adopt policies and strategies that will accelerate the adoption of the realisation of the benefits of a personalised medicine approach to healthcare.

These would include: continuation of funding of high quality academic research in disease mechanisms and the development of the EU talent pool to underpin this; stimulation of data sharing and integration to stimulate innovation; and promotion and funding of new methodologies to enable and accelerate the development of personalised medicines in Europe at both an R&D and regulatory level.

5.5 Intellectual Property management

Intellectual property (IP) does need to be addressed in any Open Innovation strategy. Although the trend in pharmaceutical R&D is towards increased knowledge sharing to accelerate innovation, competition is also an important driver of quality and speed in developing novel medicines. The right balance between sharing information and creating competition will vary along the R&D path. For example increased sharing of fundamental knowledge on disease mechanisms and biomarkers should be actively encouraged whereas profitable ownership of assets will be required to support the investment needed to develop and commercialise medicines and companion diagnostics for patients as rapidly as possible. Commercialisation considerations also need to be taken into account in any Open Innovation strategy. It is critically important that all stakeholders not only have a mind-set whereby IP is seen as important for value creation but also that this IP is appropriately valued. Overvaluation of IP at an early stage, by any party could stifle innovation; on the other hand, a closed approach to IP can also become a blocker to innovation. Digital and other industries such as telecommunications have found ways to address some of these IP issues and healthcare industries could learn from these examples.

The EU should find new mechanisms and funding tools to stimulate proactive IP management (*IP as currency*) not only within sectors but also between sectors. This will stimulate a new mind-set and could promote the idea of an Open Innovation currency where companies are rewarded and incentivised in new ways based on their commitment to proactively use their IP within and across sectors for healthcare benefits. There is also no doubt that the lack of a unified patent system is a significant barrier to innovation especially for SMEs and the EU needs to address this as a priority.

It is recommended that the EU seeks to improve the IP environment within Europe through both the enhancement of e-training of technology transfer officers, IP attorneys and others to stimulate new ways of IP transactions and publicise best practice examples and the accelerate the adoption of a single EU patent system

5.6 Commercialisation

To ensure that medical as well as economic value stems from scientific discoveries, these have to be translated into innovative clinical solutions for unmet needs that reach patients. Therefore, healthcare innovation should not only be assessed from a scientific perspective, but also in the wider context whereby clinical benefits and economic / health-outcome improvements are demonstrable and rewarded appropriately. There is a need to recognise that not all of the problems can be



resolved through research-related public funding as this will not address commercialisation barriers. Challenges to the innovation commercialisation that need to be tackled head-on include excessive regulations, price constraints, limited access to markets and the overall value of commercial markets driven by a variety of factors but also the fragmenting patient pools due to the adoption of more stratified approaches to healthcare delivery.

The issues for competitiveness in the EU can be illustrated by considering diagnostic products. Whilst the discovery and early research for complex diagnostic products is shared somewhat evenly between Europe and the US, there are striking differences between approaches to the development and commercialisation of these products. In the USA, physicians have been able to contribute to the development of and to experiment with these products both during development and after launch. In the EU, there has been very limited activity in either field. In fact in Europe, few of these companies have a significant development footprint and most have no commercial infrastructure to support their uptake. Where market entry has been attempted, a very limited amount of success has been gained only through private markets where patients are either asked to pay for the products directly, or where private insurance companies have agreed to cover the products as a way of differentiating their offering for their customers.

As ever, with new products in a new area of medicine, it remains to be seen which of these products and technologies will make the most significant contribution to the successful treatment of patients. However, if current market conditions prevail in the EU it could be anticipated that the scientists developing these products, the commercial staff promoting them and ultimately the profits they generate will be centred outside of the EU. There is a further implication from this scenario; clinicians and other healthcare practitioners will only gain experience with new innovations relatively late in the product life cycle. Their ability to influence development and potentially capitalise on it for further innovation will therefore be limited.

The situation is made more complex where different sectors are required to come together to innovate. Technology hubs in the EU could act as catalysts to bring together companies to stimulate cross sector innovation. Such hubs would improve the availability of highly skilled staff, capital and infrastructure. There are already successful precedents for this e.g. the BioAlps cluster in canton de Vaud (Switzerland) and the Hi-Tech campus at Eindhoven (The Netherlands). The availability of capital through angel funding, venture or other means will be vitally important to maintain and grow such centres. Such hubs might also help SMEs address some of the issues of scalability and access to commercialisation expertise.

There is also an interdependence between regulatory and reimbursement uncertainty and the capacity to innovate. Venture capital funds as well as large corporations are unwilling to invest where the route to commercialisation is unproven or novel. Thus, the novel endpoints and biomarkers mentioned earlier, let alone treatments for diseases and symptoms for which there is no currently approved medicine, may go unused if these commercialisation issues are not addressed.

It is recommended that the EU should find new ways of encouraging the commercialisation of innovative products in Europe through reducing regulatory and reimbursement uncertainty.

This could include measures such as:

- Reducing pre-marketing hurdles for innovative new technologies, encouraging the development of 'coverage with evidence generation' systems, develop broader clinical evidence and real life utility whilst in the market e.g. via phase IV type trials and / or partnering with on-going therapeutic clinical trials



- Supporting simpler, faster and pre-defined routes to regulatory approval for technologies.
- Supporting pre-defined criteria for reimbursement in an environment where registration is harmonised
- In addition increase focus on laboratory and reagent manufacturing quality standards e.g. ISO15189 (quality management system (QMS) requirements) and ISO13485 (medical device regulatory requirements for QMSs), helping to ensure operational excellence and quality.

5.7 Tailoring personalised medicine for the individual

In the future many more patients will be the recipients of multiple targeted interventions, for example tailored combinations of 2-3 drugs, as is already the case now for HIV patients. This will raise new challenges in understanding, which interventions used alone, or in combination, will provide the optimal balance of effect and risk for each patient treated.

Currently medical convention, as well as regulation, insists that most interventions are studied in isolation, demonstrating that each new technology is superior to existing standard practice. Little attention is paid to how the technology may be implemented in practice alongside other interventions. Increasingly it may be likely that the most significant benefits of new technologies are gained not isolation but from a sort of ‘network effect’. For example in cancer, where both the disease and patient responses are highly heterogeneous and resistance to the most effective medicine can develop, the ability to follow up therapeutic success or failure using a mix of clinical information, imaging and biomarkers and the subsequent ability for physicians to use multiple complementary therapies to interact with multiple biological pathways, may become the most effective way of managing the disease for that patient. ‘On-label only’ drug reimbursement, restricted adoption of experimental new technologies and a lack of effective and widely implemented measurement tools (to determine whether this type of clinical ‘strategy’ is on average better than traditional practice) are major barriers to adoption in the EU.

Another implication of this multifactorial approach to medicine is that the number of patients who fit a particular profile, for any combination of multiple interventions, will be much smaller even than the stratified groups used to prove the case for each technology as shown by the EU FET flagship project ITFoM , since personalised medicine can be achieved through two different approaches: (1) stratification using biomarkers and based on traditional statistics and (2) individualised or truly personalised medicine using ‘omics’ and related technologies and based on computer models and simulation. This presents major challenges for the identification and stratification of patients, the collection of appropriate data, and not least the physician’s ability to be aware of the available options and decide which combination of health technologies and medicines to use.

These existing trends create major opportunities for European stakeholders to work together in developing new strategies to help physicians and patients decide on the best therapeutic approach for their particular situation. New decision support tools and methodologies will be required to help interpret the data to provide the optimum combination of therapies for each patient. In addition, train healthcare professionals in the use and interpretation of complex diagnostic information to inform therapy choice and measure success. Better education of patients of the need for a more personalised approach i.e. acceptance of different treatments for the same disease, will also be required.

There will also be a need to encourage collaboration amongst healthcare, industry and patient groups to develop high quality ‘real world’ measurement tools, such as registries and high quality

and rich historical databases, to enable the comparison of new technologies with existing medical practice.

It is recommended that there is a focus on the development of education and communication initiatives to position 'Personalised Medicine' in the lexicon of health care provision including education of patients and healthcare professionals

Taking the global lead on the development and clinical implementation of personalised health technologies, with the explicit aim of individualising therapy for the benefit of the patient, will significantly enhance the competitiveness of the EU within the global economy.

The wide range of companies and technologies within the EU, alongside well-integrated public healthcare systems in individual markets, provides a rich seam for Open Innovation initiatives in this sector. The EU should consider how best to foster collaboration at all levels of the value chain to incentivise academics, investors and SMEs to work together and with larger corporations to capitalise on basic research, with the aim to accelerate the adoption of personalised medicines and other healthcare technologies, to effectively tailor medicine for each individual citizen. An appropriate measure of success in this area, would be a comparison of development spend and commercial sales of a basket of new technologies in the EU versus the USA.



Chapter 6

Healthcare delivery: Increasing the focus on preventive health and wellness

Contents

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6.1 Preventive Health and Wellness

This chapter focuses on preventive health and wellness, including its relevance and why and how it needs to become fully integrated into healthcare research, policies and strategies. It discusses the potential, but somewhat missed opportunities for preventive health initiatives to improve the health and wellbeing of European populations and reduce the financial burden on healthcare systems. Some of the barriers and challenges that inhibit the success of preventive health are outlined and in the final section, recommendations are made for a European Open Innovation approach to further work and research.

The following top-level recommendations are made:

- Explore the added value of a European OI Preventive Health Consortium, to include a broad range of players from a diversity of sectors, industries and bodies including patient groups. Ensure that this consortium works with any existing programmes, to avoid unnecessary duplication, address gaps, and maximise opportunities.
- Commission rigorous and systematic research on successful preventive health programmes and initiatives to identify new ways of empowering citizens to adopt and apply preventive approaches to their own health. This research should encompass healthcare systems, political agendas, education, accessibility of prevention, incentives and health-economic benefit, research and innovation and ethics.
- Focus research and work on specific healthcare challenges that are a priority across Europe and could demonstrate some sustainable ‘quick wins’ from an economic or reputational perspective. An example of this would be to include lifetime vaccination as part of a Healthy Aging programme.

6.2 Context: ‘The future of healthcare delivery will be very different to the past’

Demographic changes and economic challenges across Europe mean that the current healthcare paradigms of focusing on curative medicine will be wholly unsustainable. Alternative healthcare delivery models need to be considered as the existing methods will not adequately address these unprecedented challenges or support the future health of our nations.

6.2.1 Increasing pressure to focus on preventive health and wellness

There is increasing evidence to show that many of today’s diseases and their associated complications could be prevented or significantly reduced through preventive health and wellness initiatives. Further evidence demonstrates that, whilst initial investments will inevitably be required, over the longer term, an increased focus on this agenda offers opportunities to significantly reduce the overall costs of healthcare provision. That is not to imply that advances in curative healthcare are not essential, but that we also need to increase our efforts and investments in preventive healthcare and wellness.

Within Europe, public health initiatives such as immunisation against infectious diseases are now commonplace predominantly in the paediatric setting. More recently the focus has shifted to helping people manage or eliminate risk factors that lead to chronic disease, which is now the leading cause of death among industrialized nations. For example, somewhere in the region of 40 to



50 percent of premature deaths are attributable to health behaviours such as smoking, poor diet, and inactivity.

“Personal health behaviours are the primary determinant of disease, disability and death and primary drivers of healthcare costs. Prevention of illness, injury and associated risk factors is the ultimate cost trend mitigation strategy.”

Michael D. Parkinson, M.D. Former president of American College of Preventive Medicine¹

According to the World Health Organisation (WHO) (2004)² the leading global risks for mortality are high blood pressure (responsible for 13% of deaths globally), tobacco use (9%), high blood glucose (6%), physical inactivity (6%), and overweight and obesity (5%). These risks are responsible for raising the risk of chronic diseases such as heart disease, diabetes and cancers, affecting countries across all income groups. Eight risk factors (alcohol use, tobacco use, high blood pressure, high body mass index, high cholesterol, high blood glucose, low fruit and vegetable intake, and physical inactivity) account for 61% of cardiovascular deaths. Combined, these same risk factors account for over three quarters of ischemic heart disease: the leading cause of death worldwide. Tobacco smoking alone causes 71% of lung cancer deaths worldwide.

Table 1 illustrates the top ten risk factors associated with chronic disease both worldwide and for higher income countries: the latter includes the majority of European countries. It is estimated that the prevalence of chronic disease and number of deaths caused by these associated risks (particularly overeating and obesity and lack of physical activity), has continued to rise since the time of publication.

Table 1: Ranking of 10 leading risk factor causes of death					
World			High Income Countries (Includes majority of European Countries)		
Risk factor	Deaths (millions)	Percentage of total	Risk factor	Deaths (millions)	Percentage of total
1. High blood pressure	7.5	12.8	1. Tobacco use	1.5	17.9
2. Tobacco use	5.1	8.7	2. High blood pressure	1.4	16.8
3. High blood glucose	3.4	5.8	3. Overweight and obesity	0.7	8.4
4. Physical inactivity	3.2	5.5	4. Physical inactivity	0.6	7.7
5. Overweight and obesity	2.8	4.8	5. High blood glucose	0.6	7.0
6. High cholesterol	2.6	4.5	6. High cholesterol	0.5	5.8
7. Unsafe sex	2.4	4.0	7. Low fruit and vegetable intake	0.2	2.5
8. Alcohol use	2.3	3.8	8. Urban outdoor air pollution	0.2	2.5
9. Childhood underweight	2.2	3.8	9. Alcohol use	0.1	1.6
10. Indoor smoke from solid fuels	2.0	3.3	10. Occupational risks	0.1	1.1

Global Health Risks: Mortality and burden of disease attributable to selected major risks²

Whilst inevitably, there is variation across different European Countries, the emerging trends are similar, which means that a significant percentage of disease, disability and death could be avoided and the associated healthcare costs reduced.



6.2.2 Wellness is a key element of preventive health

The concept of 'wellness' needs to be an integral part of the preventive health agenda. Contrary to some definitions, and in particular, those encountered during the preparation of this Chapter and personal observations, wellness is not only the absence of disease or a neutral state. Rather, wellness is:

'A state of balance between physical and mental health as perceived by each individual rather than a dichotomous condition defined by the presence or absence of disease. A degree of wellness is attainable at any stage of life, regardless of the presence of disease or disability'.

Quoted at John Hopkins Embracing Health Conference, 2006

This more holistic definition suggests that a person can possess a state of wellness (mentally, emotionally and spiritually) even when afflicted with disability or chronic illness. A wellness-oriented lifestyle integrates and balances as many of the following elements as possible: physical activity, balanced nutrition, weight management, freedom from unhealthy substances and dependency, spiritual and mental health, safe behaviours, and engagement in evidence-based preventive care. Therefore, wellness is a relative term with multiple gradations rather than an all-or-nothing state of physical health.

6.2.3 Preventive health and wellness relates to everyone

The aim of preventive healthcare and wellness solutions is to improve the health and wellbeing of *everyone*, rather than only patients diagnosed with a disease or condition. However, categorising them as two distinct groups may be helpful in the context of targeting preventive health messages or solutions.

1. Individuals diagnosed with a disease whose condition and general health and wellbeing could be improved, where risks of further complications/conditions be avoided and subsequent demands on healthcare services could be reduced
2. Individuals at every stage of the lifecycle who are free from disease/have an undiagnosed condition and/or whose lifestyle puts them at risk of developing a disease,

An example of the health and wellness relating to everyone is the concept of a lifetime or life course vaccination schedule. Whilst the value of protecting children against vaccine-preventable diseases is well established, the value of vaccinating older age groups is less well appreciated. This is despite the fact that many European adults suffer death or disability caused by vaccine preventable illnesses.

In Europe there are a number of vaccine preventable diseases like influenza, pneumococcal and tetanus/diphtheria diseases that are considered life threatening for the elderly. Other diseases such as pertussis, hepatitis and herpes zoster infections have a significantly negative impact on the quality of life of, (and use of healthcare services by) those infected. However vaccination of the elderly and those 'at risk' (eg diabetics, those at occupational risk, like HCPs, etc) remains underutilised in this growing population segment and as such it has become a theme of the 'Active & Healthy Aging Innovation Partnership' initiated by EU commission at the end of 2011.

6.3 Achievements and successes in preventive health

With the exception of clean drinking water, vaccination, over the centuries has proven to be one of the most cost effective health interventions. More recently preventive healthcare has received an increasing amount of attention and there are many examples of successful preventive health innovations and solutions. It is also becoming apparent that prevention is not the sole responsibility of the healthcare profession, patients and policy makers and interest has broadened to include other



bodies, industries and sectors. Table 2 shows a few examples of preventive health innovations, including use of technology to increase physical activity and joint ventures between different sectors and industries.

Table 2. Examples of preventive health innovations

Technology innovations to increase physical activity

- Computer games that make fitness fun - Nintendo Wii's fitness programme has engaged families, including older family members, in fitness and sporting activities
- The NIKE+ FuelBand makes life a sport through innovating at the intersection of sport and data with a wristband that measures movement to motivate people to be more active

Community preventive health solutions

- Sonning Common Green Gym promotes health, fitness and wellbeing through physical work whilst improving the local environment. The intervention transforms health pathways, such as obesity, diabetes, CVD and depression.

Joint venture preventive health innovations

- MyHealthCounts, (sponsored by AVIVA and with the involvement of several organisations) offers a 'roadtohealth Q Score'[™] to show how an individual's health compares with 100 people of the same age, race and gender and provides guidance and motivation to become as healthy as possible
- UK Change4Life faces the challenge of getting families to change their lifestyles. Government bodies work in partnership with national partners, including commercial brands, and NGOs, using brands to 'talk to people and influence their behaviour'
- Private companies and public sector organisations have combined resources and expertise to develop entire housing communities through Delivering Assisted Living Lifestyles at Scale (DALLAS)

6.4 Challenges and barriers to preventive health solutions

Despite recent advances and successes, preventive healthcare has far from achieved its full potential. The practice of preventive health is fragmented and often ineffective and our healthcare systems are plagued with missed opportunities. The fact that it is so complex and intractable has resulted in inaction of some key players, including individuals who are required to make lifestyle changes. It is not surprising therefore, that challenges and barriers have been identified that stand in the way of preventive health in general, and an Open Innovation approach in particular, realising their full potential and delivering the full range of benefits to multiple stakeholder. Examples of some of the identified barriers and challenges are summarised in table 3. Whilst this is an extensive list, it is not exhaustive: there are other challenges and barriers that may be specific to a particular disease, condition, societal group, environmental context or national culture.



Table 3: Challenges and barriers to preventive health	
<p>A mindset focusing on today's problems and short-term gains.</p> <ul style="list-style-type: none"> • <i>Political agenda</i> - Preventive healthcare requires a longer term solution with benefits often not realised for years and not during a Govt's term • <i>Individuals and society</i> – focus on today and do not realise or ignore the consequences of current behaviour on future health. Some believe that either, 'it is not within my control' or 'it won't happen to me' 	<p>Time</p> <ul style="list-style-type: none"> • <i>Doctors and healthcare professionals</i> have limited time with each patient and their priority is to deal with the immediate problem presented. • <i>Primary care physicians</i> usually only see their patients when they are ill, thus there is no opportunity to give preventive advice • <i>Individuals</i> may lack time to adopt a healthier lifestyle: many people say 'they are too busy'
<p>Costs of providing preventive healthcare</p> <ul style="list-style-type: none"> • <i>Government</i> – economic crises have resulted in cuts rather than investments in public sector spending. Preventive health may not be perceived as an immediate priority • <i>Individuals</i> may feel that they cannot afford preventive healthcare – e.g. healthier food options, gym memberships, other healthy activities • If public money does not pay for preventive health, who does? Whose responsibility is it? 	<p>Lack of <u>appropriate</u> knowledge/information</p> <ul style="list-style-type: none"> • Information and guidance on preventive health are not always appropriately written or distributed. They are often written for a reading age beyond that of those who need it most. • Doctors and healthcare professions may not fully understand the information themselves. They often receive conflicting information and without evidence, may be reluctant to advise their patients
<p>Lack of or the wrong incentives</p> <ul style="list-style-type: none"> • Providers (e.g. GPs, primary care physicians) may not be financially reimbursed for providing preventive healthcare, particularly in privately funded healthcare systems. • Commercial companies, have little incentive to produce and provide healthier products and services, And there is limited public demand without huge marketing and advertising investments. Pressures of social and environmental responsibility, without financial rewards, are insufficient to motivate most large corporations 	<p>Behaviour is resistant to change</p> <ul style="list-style-type: none"> • Whilst health promotion and disease prevention require personal action, many find it hard to shed unhealthy habits or to adopt new healthier ones. Even with all of the resources available, there is often insufficient motivation to change longstanding behaviours and even less motivation to sustain those changes • Doctors, healthcare professionals and providers, politicians, public and commercial organisations and societies are also reluctant to make the behaviour changes that are required.
<p><i>Note: include barriers and challenges to Open Innovation – either insert here, or make references to previous chapters</i></p>	

6.4.1. Technology is only part of the solution

Some of the most innovative preventive health solutions rely on technology as mentioned in previous chapters (for example, mobile telephone apps, health and fitness monitoring devices, health information websites, computer technology games, such as the Wii Fit). Even simple reminder solutions to attend medical appointments, take medication, vaccination reminders etc., rely on mobile phone technology. These may be appropriate for some, the computer literate, 'technology savvy' and the more affluent, but they exclude some of the most vulnerable groups in society (e.g. proportions of older people, those with learning difficulty, the less well off) who might benefit most from preventive health initiatives. The healthcare providers and suppliers need to ensure that a range of solutions are explored, including some that are not so reliant on technology to engage with these groups and include community groups/councils/charities in the Open Innovation team.



6.5 Fundamental behaviour and attitude changes are required

6.5.1 Closing the gap between what people know and what people do

Unlike curative healthcare, where advances may rely on finding a new drug or technology to treat or cure a disease, which in turn may require massive investments and years of research, development and testing, many effective preventive health solutions already exist. The problem lies in their adoption and a major contributory factor to the adoption problem, is failure to implement and sustain the recommended behaviour changes. The problem also lies in our attitudes and the way we think about preventive health. Psychological theories^{3,4,5} have shown that a change in attitudes and beliefs is necessary for sustained behaviour change. Past examples illustrate how broad attitude change over time can significantly change behaviour (for example, use of seatbelts, sunscreen and more recently smoking cessation).

In essence, the greatest challenge and opportunity for preventive health innovation lies in closing the gap between what we know and what we do. This includes attitude and behavioural changes of many different stakeholder groups (e.g. healthcare professionals and providers, private companies, such as retail and food outlets, public sector bodies, politicians and policy makers, all forms of media and the public) as well as individuals at whom a preventive health solution is targeted.

The following two sections discuss how two factors (rewards and responsibility) may encourage the necessary behavioural changes. These are by no means the only factors that influence behaviour change and others such as self-efficacy⁶ and ease or difficulty of performing a behaviour⁷, could be considered for further work on preventive health. Rewards and responsibility have been identified as two factors that if applied to *all* stakeholder groups, could create significant leverage for change.

6.5.2 More effective incentives and rewards with shortened timescales

The principle of reciprocity means ‘give and take’. It is the law of giving for something received and expecting a return for something given. Therefore, individuals who are expected to change behaviour (the give) may be motivated to do so only if they perceive there to be a fair reward or incentive (the take). Evidence suggests that current incentives and rewards may be perceived as insufficient exchanges for what is expected and/or may not happen within a short enough timescale. For example, a diabetic patient who is morbidly obese will not experience the rewards of dieting and exercise (better health, body image, self-esteem etc.) for many months and consequently, often returns to old behaviours that offer more immediate gratification. Other examples include: primary care doctors who are not compensated financially, or otherwise, for providing preventive healthcare; politicians who may not see the results of policy changes and investments in preventive healthcare during their term.

6.5.3 Raising awareness of responsibilities

A typical preventive healthcare approach has been to raise awareness of the consequences of behaviour or to create a sense of dissatisfaction with the way things are today, for example, smoking cessation campaigns, the long term effects of obesity and excessive alcohol consumption. There have been some successes but overall, these strategies have failed to change behaviour on the scale that is needed. We know that rational stern warnings from Governments about risking future poor health outcomes have a limited ability to influence behaviour, no matter how severe the consequences may be.

A different approach is called for. Connecting preventive behaviours with a sense of responsibility (at an individual, family, corporate, government level) might offer a better lever to engage individuals and stakeholder groups in the preventive health arena and to inspire and motivate sustained behaviour change.



This strategy has already been successfully applied to a number of health issues. For example, a UK television documentary, 'Honey we're killing the kids' was an attempt to increase parental responsibility for their children's future and to encourage them to support children with lifestyle changes.

More recently, there have been attempts to encourage social responsibility amongst large corporations. Social responsibility is an ethical ideology that an entity, be it an organization or individual, has an obligation to act to benefit society at large. There are examples of success, such as Wal-Mart's Green Revolution, AREVA, Tyson Foods' commitment to relieve childhood hunger, Greenopolis and recycling and Haagen Daz's honeybee conservation. Whilst most examples relate to environmental and energy issues, they are likely to offer lessons that could be applied to preventive health and wellness.

6.6 Recommendations for preventive health research and development

Preventive health and wellness is a huge and complex agenda with numerous priorities but it offers significant opportunities for people and health systems in the future. . There are few, if any, quick fixes and there is a need to utilise many different ideas, experiences and modalities to ensure success. The recommendations made here include priority topics that potentially offer the most leverage for advancing the preventive health agenda.

The 3 top-level recommendations are as follows.

- **Explore the added value of a European OI Preventive Health Consortium**, to include a broad range of players from a diversity of sectors, industries and bodies including patient groups. Ensure that this consortium works with any existing programmes, to avoid unnecessary duplication, address gaps, and maximise opportunities.
- **Commission rigorous and systematic research on successful preventive health programmes and initiatives** to identify new ways of empowering citizens to adopt and apply preventive approaches to their own health. This research should encompass healthcare systems, political agendas, education, accessibility of prevention, incentives and health-economic benefit, research and innovation and ethics.
- **Focus research and work on specific healthcare challenges that are a priority across Europe** and could demonstrate some sustainable 'quick wins' from an economic or reputational perspective. An example of this would be to include lifetime vaccination as part of a Healthy Aging programme.

More detail sits behind these 3 top –level recommendations, and this detail is given below and summarised in figure 1

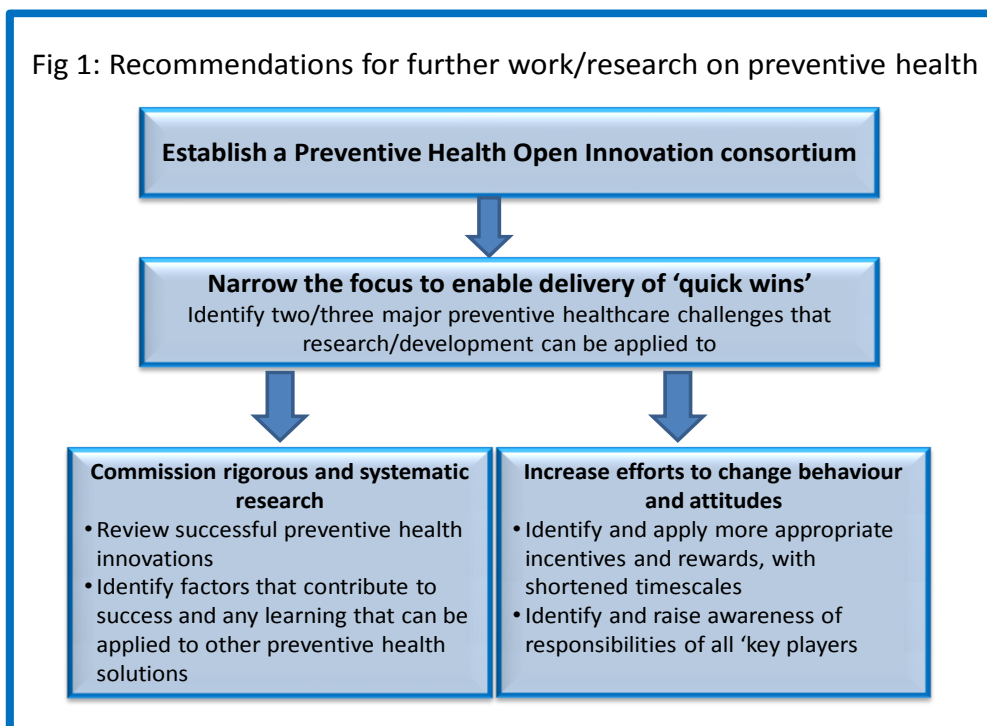
6.6.1 Establish a European Preventive Health Open Innovation consortium

No one player can solve the problem. Only coalitions of companies and bodies who can pool resources and combine expertise, access and innovation to target preventive health challenges are likely to succeed. A European OI Preventive Health Consortium should be established and it should include a broad range of players from a diversity of sectors, industries and bodies that may or may not have previously been involved in this area. Indeed the European Union has already tackled these challenges in a related areas asking for the development of European Best Practices in genomics. The Public Health Genomics European Network (PHGEN) developed guidelines, which recently had been endorsed by the EU Member States and relevant European organisations and institutions such as EMA (Declaration of Rome, www.phgen.eu). These guidelines will be implemented in the EU Member States in the next few years and can serve as the basis for such a European Preventive Health Open Innovation consortium.



6.6.2 Focus research and work on specific healthcare challenges

Research and development will be more impactful if it focuses on two or three specific health challenges that are a priority cross Europe. Interest and participation in the preventive health challenge is likely to increase if we can show some sustainable ‘quick wins’ that have a visible impact in these two or three areas. A challenge for a European OI Preventive Health Consortium is to find a ‘common cause(s) that will unite a range of companies and bodies, draw on the expertise and capabilities of each party and offer a clear payback, whether commercial or reputational.



6.6.3 Commission rigorous and systematic research on preventive health

A more systematic and rigorous approach to preventive health research and evaluation is required. Whilst preventive health initiatives are often evaluated, typically these focus on adoption rates, the impact on those taking part, the barriers and return on investment. Research and evaluation do not always focus on identifying the critical success factors so that preventive health solutions might be implemented more widely and knowledge can be shared more openly and applied to different contexts and different health challenges. .

The European OI Consortium should commission research to:

- Systematically review successful preventive health solutions and innovations (in the two or three agreed priority areas) to identify their key principles of success - *how* and *why* they have worked
- Identify ways to share that knowledge and learning more widely and freely to: increase adoption rates; spread existing preventive health solutions to other communities and countries; apply it to different contexts and different healthcare problems; encourage participation in preventive health from a wider group of stakeholders and break down some of the barriers to Open Innovation

6.6.4 Increase efforts to influence behaviour and attitude change

To increase the adoption rate of preventive health solutions to the level that is urgently needed will require increased efforts to influence the necessary behaviour and attitude changes. We need to

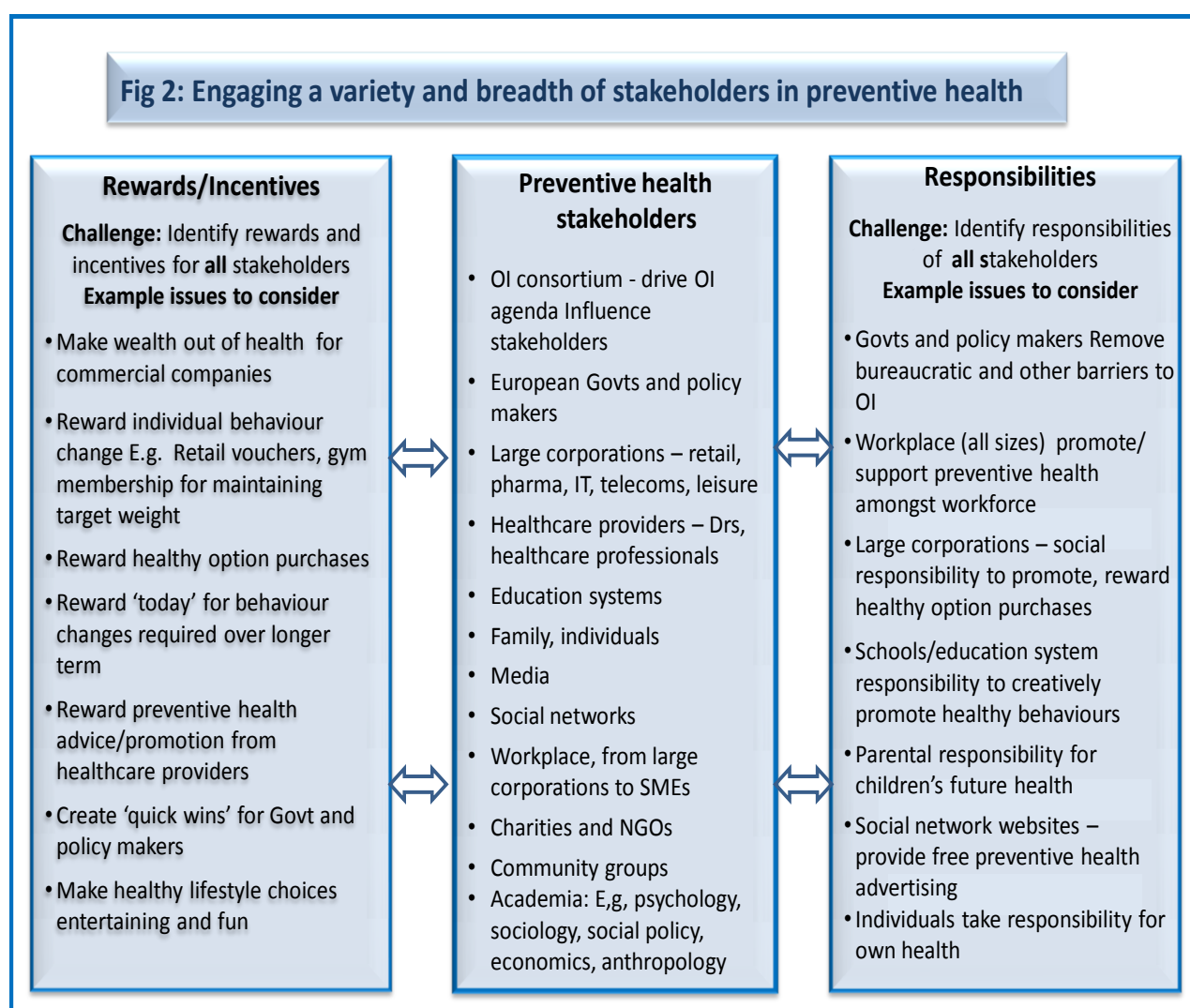


encourage *all* stakeholder groups to become part of the solution rather than part of the problem. A priority for further work and research is to:

- Identify more appropriate and relevant incentives and rewards for *all* stakeholders with a particular focus on shortening the time delay between behaviour and reward
- Explore how examples of creating a sense of responsibility (individual, familial, corporate, political, social etc) can be applied to preventive health.

An example would be to provide rewards and incentive to large corporations (e.g. food retailers and fast food outlets) for engaging in preventive health and promoting healthier options and encouraging them to become socially responsible towards the communities they serve. For smaller companies, we might explore how ‘social entrepreneurship’ can be encouraged and applied to preventive health.

Figure 2 provides further examples of some of the issues that might be explored with some of the key stakeholder groups. These are intended only to stimulate thinking about how a more innovative approach to preventive health through Open Innovation could be adopted.



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Chapter 7

Building an Open Innovation ecosystem in Europe for healthcare

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7.1 Building an Open Innovation Ecosystem

This chapter presents an analysis of the current EU Healthcare Innovation ecosystem, viewing stakeholders within the sector as highly inter-dependent where the flow of technology and information among people, enterprises and institutions is key to the innovation process. The chapter demonstrates that breakthrough innovation often occurs at the interface of different sector participants, and the term 'innovation ecosystem' is an appropriate term to describe the inter-dependencies of these sectors. Better understanding of this innovation ecosystem highlights key areas for improvement based on the principles of Open Innovation for example in data sharing, inter sector IP exploitation and new collaborative models. Ultimately, the chapter shows that the interdependencies between the various players in the healthcare sector are much greater than have been previously anticipated. Taking an ecological view of the challenge to innovate, it is proposed that the fates of the leading protagonists in the “innovation ecosystem” are intricately interconnected with the smallest players. The following recommendations are made to support the development of a robust Open Innovation healthcare ecosystem in the EU:

- Actively support the development of Crowd Sourcing and Crowd Funding to develop critical mass, linking the diversity of expertise across the European Union to collaboratively address major challenges in health.
- Develop a cross directorate task force to review funding of the entire innovation ecosystem, address regulatory barriers and develop incentives (such as open innovation credits, common IP frameworks and building public private partnerships) to encourage individuals and organisations to participate in an open innovation health ecosystem to generate value and benefit for European Citizens and European health care companies.
- To build on successes such as the IMI and actively engage with existing stakeholder groups including government, industry, patients and carers, funders and financiers to place European citizens at the heart of the open innovation eco-system.

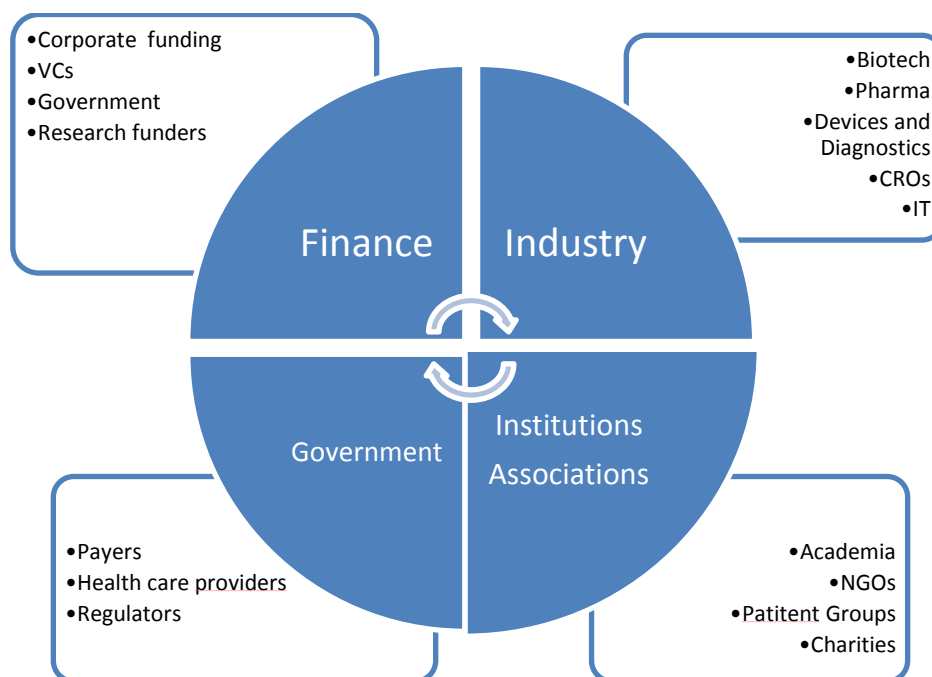
7.2 Who are the potential participants in an Open Innovation ecosystem?

As described in chapter 2, the term *Open Innovation* was coined by Henry Chesbrough as recently as 2003¹, but arguably has already been widely practiced by some of the most innovative companies worldwide for a number of years. The key principle of Open Innovation of relevance to the understanding of the Open Innovation ecosystem is that innovative ideas can originate anywhere and should be able to be exploited anywhere. Importantly it also maintains that fair rights of idea ownership should be retained, but this should not be a barrier to the movement of these ideas. The latter is perhaps the key concept that differentiates Open Innovation from other forms of innovation. In a true Open Innovation ecosystem, ideas should not be monopolised by one individual or organisation. This does not mean that intellectual property (IP) is not important in Open Innovation but rather is proactively managed to maximise its exploitation. When a concept/product is exclusively owned and controlled, its potential to evolve is greatly diminished. Returning to the ecosystem analogy, it is in effect removed from the gene pool.

In a healthy ecosystem, populations are **interdependent**. That is, they depend on each other in a delicate balance for survival – currently there are many potential players in an Open Innovation ecosystem for healthcare in Europe (Figure 7.1). Europe has a real opportunity to capitalise on this diversity to stimulate a vibrant Open Innovation ecosystem and can build on some examples of best practice seen in other sectors (see section 7.2).



Figure 7.1. Key Participants in the Healthcare Open Innovation Ecosystem



7.3 Importance of a robust Open Innovation ecosystem for healthcare

The Open Innovation approach to healthcare is reliant on the dynamics of the entire healthcare community from discovery to the full range of healthcare delivery whether in the clinic or the home. Now that the gap between industry and public domain innovation appears to be narrowing, Open Innovation is a natural and intuitive response to build stronger public-private partnerships. In the case of drug discovery this is happening both in the US with the NIH-funded, National Center for Advancing Translational Sciences², and in the EU with the Innovative Medicines Initiative³. In many cases, Open Innovation and open access strategies may represent the only hope for disease areas with a significantly higher record of failure to discover new drugs compared to the norm, such as the psychiatric disease area⁴. Despite considerable societal need, many large pharmaceutical firms have now ceased all R&D programmes in psychiatry, because the cost of failure is perceived to be too high⁴. Conversely for the wider healthcare ecosystem, the failure of industry to engage in the development of more efficacious treatments represents an opportunity cost for healthcare budgets. Again, taking the example of mental health, psychiatric diseases are arguably approaching neglected disease status, despite being the number one health burden in the EU in terms of direct and indirect costs⁵.

As mentioned in chapters 5 and 6, in terms of later stage clinical development and downstream delivery of healthcare, there are real opportunities to bring together a range of different technologies and participants. These include defining new outcome measures especially in the area of prevention e.g. the use of mobile technologies for collection of data, diagnostics and biomarkers for patient stratification, improved patient reported outcome measures, novel trial design etc. There are currently a number of barriers to this especially in terms of regulatory oversight and the EU needs to consider how best to organise to accelerate the approval and adoption of new technologies within the healthcare sector especially those that combine technologies. In addition funders may need to address the lack of available incentives to stimulate the interaction across sectors and to capture the value of the investment in basic research for downstream development and marketing. This might be achieved by encouraging the establishment of innovation hubs, taking a lead from the initiatives such as the Phillips High Tech Campus (Eindhoven, NL), which has proved



highly successful in the incubation of innovation, venturing, and attracting new investment into the campus and which has helped transform this company's activity in health technologies in remarkably short time (Figure 7.2; www.hightechcampus.com).

Figure 7.2. The Phillips High Tech Campus: A model Open Innovation Ecosystem



7.4 Organising for Open Innovation

For all participants in the Open Innovation ecosystem there need to be clear cultural and business objectives both internally and externally. These need to be aligned so that there are incentives at all levels of the organisation, and therefore the ecosystem, to stimulate interaction and knowledge sharing. Collaboration is an integral component in open innovation and thus a corollary of this is that competition between individuals and institutions forms barriers to the flow of ideas in open innovation eco systems. We propose the creation of a cross directorate task force to look into ways of overcoming barriers to open innovation and to help create enablers such as commons templates for IP and knowledge exchange as well as to developing incentives to engage in an open innovation ecosystem. Support for organisations and individuals engaged in the development of cross sector working and public private partnerships should be encouraged and key performance metrics for open innovation systems will also need to be developed to measure and evaluate progress.

Failure to appreciate the importance of all participants in the innovation ecosystem, can lead to one of the commonest sources of failure in the implementation of Open Innovation strategies – a lack of real alignment in positive success metrics.

A common theme identified by the Innovahealth panel was a general lack of incentives for employees to work on Open Innovation if this was not explicitly part of their jobs. Although many companies have strategies that involve a strong Open Innovation component, many of these do not follow the example of companies such as Google in allowing employees a certain amount of work time ring-fenced for innovation. In the case of Google this is amounts to 20% of a person's time.

The practice of Open Innovation by employees and even by organisations could be treated in a similar way to CPD (Continuous Professional Development) credits. This would create a form of



currency for Open Innovation, thereby further energising the ecosystem. The system might also work in a similar manner to carbon credits. The Innovahealth panel envisaged a possible situation where the EU could directly incentivise demonstrable Open Innovation activities, by offering companies, academics etc. “Open Innovation credits”, which could then be used for something tangible, e.g. priority for research funding schemes or additional funding for enhancing bringing together or extending collaboration across existing projects.

7.5 Building on existing EU programmes to support Open Innovation

The EU is already providing some wide-ranging support for Open Innovation activities in the pharma sector with the Innovative Medicines Initiative. The Innovahealth panel suggested that an extended IMI-like initiative should be considered across the healthcare and associated sectors (e.g. IT, medical devices, diagnostics and consumer). This could offer complementary synergies with the existing framework initiative and encourage more direct engagement of industry with EU innovation on an in-kind basis.

7.6 New models for healthcare innovation: Crowd science

The success of an innovation strategy is critically dependent on the visibility of “external innovations” within and across fields, so that they can be recognised and adopted. Crowd Science is a key Open Innovation concept to improve the visibility of the needs of innovators and innovation seekers. Whilst the concept has been implemented in many different ways, two key implementations of crowd science are considered here:- crowd sourcing and crowd funding.

From the point of view of innovation seekers, “crowd sourcing” is a process where tasks traditionally performed by specific individuals are opened up to a group of people or community (crowd) through an open call. Research funding agencies, such as the EU framework programmes, The EU Innovative Medicines Initiative and UK Technology Strategy Board (TSB) are already working in this way when they release a call for proposals in a specific research area. Taking the TSB as an example, it serves an important UK national role both as a direct funder but also as an intermediary for other UK national funding schemes. This presents innovators with a single portal to most UK national funding schemes. Increased funding at the interface between sectors would further increase innovation. Similar national and EU-wide initiatives should be encouraged and supported by the EU.

The other concept is “crowd funding”. This describes an open call process to offer services or promote available capabilities that can be used by other organisations. Put simply crowd sourcing requests a service, while crowd funding offers a service.

Both approaches have already been applied to across the spectrum of healthcare innovation from discovery to the clinic with some success. A good example of the crowd funding approach is DrugDev.org (Table 7.1), which uses social networking technology to publicise the availability of over 60,000 clinical trial investigators in 93 countries. The database includes a capability to provide feedback on investigators' trial recruitment capabilities, infrastructure and quality. In less than 2-years DrugDev.org has grown from a start-up to the biggest network of independently rated research sites in the world, transforming the way many major CROs and pharmaceutical companies conduct study feasibility, site identification and start-up activities, with quite a dramatic effect on timelines and cost. A well-tailored crowd funding approach to publicise translational healthcare researchers and their innovations does not yet exist, but stimulating such activity within the EU through existing funding bodies could provide an impetus to Open Innovation in translational research.

Crowd sourcing is probably the most successful Open Innovation concept to date e.g. a good example is InnoCentive (Table 7.1), which was originally developed at Eli Lilly to use the internet as a



route to discover external solutions to challenging internal research problems. InnoCentive became the first global internet-based platform designed to help connect Seekers, those who had difficult research problems, with Solvers, those who came up with creative solutions to these problems. Another Interesting variant is challenge led innovation such as the Crack-it initiative lead by the National Centre for Reduction and Refinement (NC3R). In this case a challenge is posed by industry and teams including other industry participants are either invited to co-sponsor and refine the challenge which encourages cross sector teams to form and build multidisciplinary teams to address the challenge (<http://www.crackit.org.uk/>). Similar crowd sourcing concepts have now been widely adopted throughout healthcare by diverse companies including GE Healthcare, Johnson & Johnson and Procter & Gamble. The U.S. Patent and Trademark Office have also notably applied crowd sourcing to the patent review process with their Peer to Patent Community Patent Review project (Table 7.1), which allows scientists to submit prior art, which might invalidate a patent application. Actively supporting the development of Crowd Sourcing and Crowd Funding to develop critical mass, will be critically important in leveraging and linking the unique diversity of expertise across Europe and will be a driver in maintaining Europe at the forefront of global efforts to address major challenges in health.

An emerging trend in the power of the crowd comes from patients themselves who are using social media and the internet to connect and share knowledge in new and innovative ways. Patientslikeme (Table 7.1) is an online social networking forum that allows patients to share experiences of all aspects of treatment and healthcare. When a small Italian study reported that lithium carbonate had the potential to slow the progress of Amyotrophic lateral sclerosis (ALS), hundreds of Patientslikeme users started taking the drug under the supervision of their physicians⁶. They were unable to replicate the promising findings of the preliminary study, but nevertheless the power of sharing data to rapidly advance healthcare was clearly demonstrated. The EU should consider how best to harness and incentivise the involvement of individual patients and patient organisations in healthcare innovation across the whole value chain from basic R&D through to the delivery of healthcare solutions by healthcare providers. Linking patients into an open-innovation eco system will help leverage the diversity across Europe place its citizens at the heart of healthcare innovation and herald in the era of personalised medicine.

7.7 Partnering to cross the “Translational Valley of Death”

The Translational “valley of death” is a widely used concept referring to the widening gap between advances in basic science and the practical application of that knowledge into the clinic⁷. A major factor at the heart of the translational gap is a poor understanding of how to translate clinically relevant parameters into basic science programmes as well as an inability to take reductionist science to relevant outcomes in the population. Historically public domain resources for healthcare research have been relatively under-resourced with inconsistent quality control. This situation is rapidly changing. Governments and other science funding organisations have substantially increased healthcare research funding to facilitate access to both data and translational research facilities. Examples of such investment include the NIH molecule libraries initiative, PubChem and the Wellcome Trust funded ChEMBL database (Table 7.1). Encouragingly a recent (crowd sourced) appraisal of the quality of the data was very positive⁸. This trend looks set to continue. The increased focus on good public domain data and resources, combined with the increased movement of staff from industry to the public domain may offer an important opportunity to further improve partnership between public and private sectors. This is also being reflected by the announcement of major open access drug discovery projects, such as Arch2POCM (Table 7.1), which aims to use a crowdsourcing approach to take small molecules for Autism, Schizophrenia and Cancer into man⁹. Specifically the way in which these newly created resources can be accessed and used both within



and across specific sectors to stimulate innovation in healthcare requires the creation of an open innovation based ecosystem.

The EU should consider how to best to facilitate these types of data sharing and build on the success of projects such as the IMI and other initiatives funded under the Framework and other programmes and actively engage with multiple stakeholder groups including government, all industry sectors, patients and carers, funders and financiers to create an open innovation ecosystem.

7.8 New models for prevention

A critical challenge for the EU is the need to stimulate new approaches to disease prevention and wellness. This will challenge existing clinical trial and regulatory frameworks and needs a long term approach that is best delivered at an EU level. These are discussed in more detail in chapters 5 and 6. The EU FET flagship initiative ITFoM would provide such an opportunity for Europe leading the global way.

7.9 Key Benefits of the Open Innovation ecosystem

The benefits of a robust Open Innovation ecosystem are self-evident for the healthcare sector. By promoting increased collaboration across the sector, increases should be seen in knowledge transfer, transfer of skills and increased mobility of researchers within the sector. In combination these should promote greater innovation in the sector, create value and a more efficient health care system.

An efficiently functioning Open Innovation ecosystem will also help to promote the competitiveness of EU R&D and EU industry within the global economy. Harnessing the power of an open innovation system across Europe will make European healthcare companies more competitive by access to better resources better phenotyped populations and provide a means to anchor value locally with its originating partners while still allowing its exploitation across the innovation ecosystem. The EU already has unparalleled programmes for promoting and funding innovation in healthcare, such as the framework programme and the IMI. These programmes should continue to be fully funded with an emphasis on how these instruments can be used to drive collaboration across the entire innovation ecosystem.

The Increased innovation fostered by a robust healthcare innovation ecosystem should have clear benefits for healthcare delivery by promoting the development of safer, more effective medicines, and advanced clinical care in the form of improved molecular diagnostics and imaging to support individualised healthcare.

7.10 Recommendations

The following recommendations are made to support the development of a robust Open Innovation healthcare ecosystem in the EU:

- Actively support the development of Crowd Sourcing and Crowd Funding to develop critical mass, linking the diversity of expertise across the European Union to collaboratively address major challenges in health.
- Develop a cross directorate task force to review funding of the entire innovation ecosystem, address regulatory barriers and develop incentives (such as open innovation credits, common IP frameworks and building public private partnerships) to encourage individuals and organisations to participate in an open innovation health ecosystem to generate value and benefit for European Citizens and European health care companies.



- To build on successes such as the IMI and actively engage with existing stakeholder groups including government, industry, patients and carers, funders and financiers to place European citizens at the heart of the open innovation eco-system.

Table 7.1. Open Innovation Resources for Healthcare

Resource	URL
Open Standards and Infrastructure	
Pistoia Alliance (Pre-competitive standards for drug discovery)	www.pistoiaalliance.org
Chem2Bio2RDF (Semantic Web in Systems Chemical Biology)	chem2bio2rdf.org/
Open Access and Open Innovation Healthcare R&D resources	
ChEMBL (Wellcome Trust funded drug database)	www.ebi.ac.uk/chembl
The Structural Genomics Consortium	www.thesgc.org/
SAGE Bionetworks	sagebase.org/
Open PHACTS (IMI project building open drug discovery resources)	www.openphacts.org
EMVDA Research Reagent Repository (Malaria Vaccine Dev.)	www.malariaresearch.eu/
Arch2POCM (Open access drug discovery programme)	www.arch2pocm.org/
The Innovative Medicines Initiative	www.imi.europa.eu
Crowdsourcing, Crowdfunding and Social Media in Drug Discovery	
DrugDev.org (Database of >62K worldwide clinical trial sites)	drugdev.org
GrowVC (Global crowdfunding platform)	www.growvc.com
Innocentive (Highly successful crowd sourcing tool)	www.innocentive.com
Patients like me (Patient led disease treatment community)	www.patientslikeme.com
Peer to Patent (Crowdsourcing to evaluate patent prior art)	peertopatent.org/

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Chapter 8

Education and Training

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8.1 Education and Training

Future growth and prosperity within Europe is dependent on many factors, the most important of which is the education and training of the whole of the health ecosystem, from patients to researchers through to policy makers and funders.

The following recommendations are made to support the development of an effective education and training programme for OI healthcare in the EU including recommendations on education from the other chapters presented here:

- Review the existing programme of education and training available in the EU, IMI and other related bodies for potential application in this area
- Create an institute of healthcare education to drive a long term strategy and then deliver programmes across the health ecosystem
- Consider the whole portfolio of education and training needed for both skills and mindsets across the whole OI Healthcare in the EU ecosystem, working with such groups as the proposed European Preventive Health Open Innovation consortium
- Increase awareness of the role of nutrition in health, by using a Euro-barometer-type survey to assess the level of awareness and identify gaps
- Focus on the development of education and communication initiatives to position 'Personalised Medicine' in the lexicon of healthcare provision, including education of patients and healthcare professionals
- Improve eHealth education and awareness across all domains
- Improvement of the IP environment within Europe through both the enhancement of e-training of technology transfer officers, IP attorneys and others to stimulate new ways of IP transactions and publicise best practice examples to accelerate the adoption of a single EU patent system



Increase efforts to influence behaviour and attitude change for preventative health

Ensure provision of professional project management training for those involved in managing PPPs.

8.2 Background

The importance of focusing on the development of talent for driving innovation has already been demonstrated in several countries both within and without the EU. In the late 1990s and early part of the 21st Century, both Ireland and Singapore invested heavily in developing the talent at school and university level. The results of this focus has driven their respective knowledge based economies and produced a dramatic increase in home grown talent¹. The same is also true for Finland. Education and training are the keys to future growth and prosperity in Europe especially with regards to healthcare. In innovation in the health sector, the whole of the health ecosystem i.e. patients, their families, carers, health care professionals of all types, researchers and scientists, industry, regulatory, academia and funders, will need to focus on high quality education and training. This education and training is needed to address both new capabilities, and changes in mindset for effective Open Innovation. Whilst some of these groups have historically been accustomed to education and training forming the cornerstone of their development, many have not.

Open Innovation in health must have education as an overarching strategy for all involved in the chain from researcher to the end user and their support. It will require the development of new mind sets and the capabilities to access and use the new tools and technologies that are available globally. The cultural change required, especially in some academic and government institutions, as well as in business will be enormous if the true potential of Open Innovation is to be realised. This will require a long term strategy, investment and incentives. The diversity within the EU can be a real resource for Open Innovation but only if a knowledge base exists alongside the talent to leverage it.

Open Innovation embraces a number of new and different ways of working which require skill sets that are not normally seen as critical in healthcare generally and R&D in particular. These include excellent communication and dissemination skills, project leadership and coordination and excellence in collaboration and teamwork. They will be required alongside the more traditional, technical, commercial and policy roles. In addition creating the framework which facilitates the hiring and career progression of 'non-traditional' employees will also be important. Firms, governments and institutions tend to look for and hire those people who are a good organisational fit for the current organisation when the focus might be of hiring precisely those people bring something completely new and a different perspective and knowledge base². These barriers to change should not be underestimated and will require incentives and commitment within the EU.

Such an education and training framework will also have to ensure that the broadest elements of societal need are addressed. This strategy will ensure that education and training for all involved will be relevant, focused, engaging and appropriate. This will be the key to successful delivery of all the aspects of the Open Innovation strategy presented within this document.

8.3 Opportunities

Fortunately there already exists a broad range of existing initiatives within the EU, such as the Innovative Medicine Initiative (IMI), and these should be utilized and developed further where



necessary. They could be especially important in piloting new ways of working, identifying current skill gaps within the current portfolio and disseminating best practice.

These include the following:

- Intra-European Fellowships (IEF), which aims to help experienced researchers to get new skills
- International Outgoing Fellowships (IOF) which aim to reinforce the international dimension in the career of European researchers willing to acquire new skills in a top research institution based in a third country.
- International Incoming Fellowships (IIF), which aim to attract top-class researchers currently active in a third country and make them undertake research in Europe.
- Career integration grants (CIG), which aim to encourage researchers to establish themselves in a stable position in a member state or above country after a period of mobility.
- Industry Academia Partnership and Pathway (IAPP) aim to foster cooperation between public research organisations and the private sector, in particular SMEs
- Initial Training Networks (ITN) aims to improve the career perspective of early-stage researchers in both the public and private sectors
- Cofunding (COFUND) is addressed to public R&D organisations that finance and manage fellowship programmes
- International Research Staff Exchange Scheme (IRSES) aims to strengthen research partnerships between Europe and third countries

As can be seen these are predominantly, as was their design, focused on researchers and their institutions. Whilst this is beneficial to European research broadly it does not address the integration and development of the whole of health infrastructure, all the way to the end user. Open Innovation could provide the framework for initiating and integrating efforts across sectors possibly utilising the Institute described in Chapter 6.

Training in the application of new tools and technologies should contribute to 'crowdsourcing' input to innovation, enable contributors to gain generalist knowledge in order to supplement specialist knowledge. This will allow contributions to the discussion across sectors rather than simply from a specialist perspective. It should also target creating an understanding of how to work differently / more creatively so that innovation becomes more integral to business processes all along the value chain.

Understanding the value (tangible and intangible) and economics of Open Innovation efforts is also critical. Few firms have adequately paid attention to this but it is a vital part of ensuring a successful Open Innovation strategy at business level but also at a policy level. The methodologies for such an strategy should also endeavour to address how to generate commercial benefit through understanding of the nature and development of intellectual property and its' commercialisation

8.4 Recommendations and proposed pilots

The following recommendations are given to underpin the implementation of the key areas for action from the preceding chapters.

- Review the existing programme of education and training available in the EU, IMI and other related bodies for potential application in this area, identify where gaps exist and areas of strength on which future initiatives could build
- Create an institute of healthcare education to drive a long term strategy and then deliver programmes across the health ecosystem

- Consider the whole portfolio of education and training needed for both skills and mindsets across the whole OI Healthcare in the EU ecosystem, working with such groups as the proposed European Preventive Health Open Innovation consortium. This would increase the application of new ways of innovating such as crowdsourcing and accessing global knowledge for the benefit of the EU.
- Significantly increase the focus on the development of education and communication initiatives to position 'Personalised Medicine' as a keystone of healthcare provision. This should encompass the whole spectrum from early R&D through to commercialisation and delivery and would include education of patients and healthcare professionals.
- Significantly improve eHealth education and awareness across all domains so that the full benefits of eHealth can be realised as early as possible for patients and the EU economy
- To stimulate the use of IP as currency and new ways of leveraging IP, the EU should strengthen the understanding of IP and its value at all levels including government, technology transfer offices and regulators as well as industry, with an especial focus on e-learning/training. This should include dissemination of best practice and the adoption of a single EU patent system.
- Increase awareness of the role of nutrition in health, by using a Euro-barometer-type survey to assess the level of awareness and identify gaps
- Increase efforts to influence behaviour and attitude change for preventative health especially through education initiatives aimed
- With the increase in collaborative working, ensure that the EU has a skilled pool of professional project coordinators and alliance managers to ensure large scale public private and other partnerships deliver

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