



**European Cooperation  
in the field of Scientific  
and Technical Research  
- COST -**

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**Brussels, 15 May 2014**

**COST 057/14**

**MEMORANDUM OF UNDERSTANDING**

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Subject : Memorandum of Understanding for the implementation of a European Concerted Research Action designated as COST Action TD1405: European Network for the Joint Evaluation of Connected Health Technologies (ENJECT)

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Delegations will find attached the Memorandum of Understanding for COST Action TD1405 as approved by the COST Committee of Senior Officials (CSO) at its 190th meeting on 14 May 2014.

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**MEMORANDUM OF UNDERSTANDING**  
**For the implementation of a European Concerted Research Action designated as**  
**COST Action TD1405**  
**EUROPEAN NETWORK FOR THE JOINT EVALUATION OF CONNECTED HEALTH**  
**TECHNOLOGIES (ENJECT)**

The Parties to this Memorandum of Understanding, declaring their common intention to participate in the concerted Action referred to above and described in the technical Annex to the Memorandum, have reached the following understanding:

1. The Action will be carried out in accordance with the provisions of document COST 4114/13 “COST Action Management” and document COST 4112/13 “Rules for Participation in and Implementation of COST Activities” , or in any new document amending or replacing them, the contents of which the Parties are fully aware of.
2. The main objective of the Action is to develop input for future market applications in the field of health and social care by comparing and assessing models, technologies and methodologies leading to technical & process innovation, moving care from hospital to home, and connecting stakeholders to share information.
3. The economic dimension of the activities carried out under the Action has been estimated, on the basis of information available during the planning of the Action, at EUR 64 million in 2014 prices.
4. The Memorandum of Understanding will take effect on being accepted by at least five Parties.
5. The Memorandum of Understanding will remain in force for a period of 4 years, calculated from the date of the first meeting of the Management Committee, unless the duration of the Action is modified according to the provisions of section 2. *Changes to a COST Action* in the document COST 4114/13.

## **GENERAL FEATURES**

### **Initial Idea:**

Society needs to leverage advances in technology to drive the innovation required at a health and social care service level to meet the challenges posed by demographic changes and uncontrolled health care costs. The COST Action “ENJECT” will bring together business and revenue modellers, clinicians, technologists, engineers, economists, ethnographers and health researchers to help society to answer one question – how to connect therapies, patients and care-givers to deliver optimum health results in an era of stretched resources and increasing demands. A true Connected Health solution must work across countries, continents and the globe to be technically and economically viable. ENJECT will deliver unprecedented access to an understanding of Europe’s varied health systems, markets and demographics. Access to commercial players, datasets, market knowledge and policy makers across Europe will be ensured through the high profile, interdisciplinary and international experts included in this Action. ENJECT will seed cross-border, interdisciplinary teams and partnerships leading to new collaborations, improved training and professional development opportunities, knowledge and staff exchange and a European communication platform for Connected Health research.

**Keywords:** connected health, standards of care, monitoring technologies, health informatics, business models, implementation & evaluation, policy, regulation

### **A. CHALLENGE**

Society faces a major health and social care challenge: demographic changes will raise dramatically the proportion of those over 60 years of age. We will face unmanageable costs associated with chronic diseases such as cardiovascular, respiratory and metabolic disorders, and a global shortage of qualified healthcare professionals. It is clear we need to find new ways of managing health and social care throughout our lifespan.

Recent studies describe a paradigm-shift in healthcare; that preventive, pre-emptive and predictive healthcare decisions should be made in a pervasive, participatory and personalised manner. It is widely accepted that such a paradigm-shift is not possible using traditional tools and processes. Thankfully, we now live in a digital-age wherein technological innovation is occurring at an

exponential rate. Increased availability of technology, allied to the need to re- imagine healthcare, is driving a move towards leveraging that technology to deliver more efficient and cost-effective health and social care models.

### **The Connected Health Model**

The term ‘Connected Health’ is increasingly being used to describe this new technology-enabled model of healthcare delivery.

Connected Health encompasses terms such as wireless, digital, electronic, mobile, and tele-health, and refers to a conceptual model for health management, wherein devices, services or interventions are designed around the patient’s needs, and health related data is shared, in such a way that the patient can receive care in the most proactive and efficient manner possible. All stakeholders in the process are ‘connected’ by means of timely sharing and presentation of accurate and pertinent information regarding patient status through smarter use of data, devices, communication platforms and people.

The Connected Health-approach enables a shift from reactive, to proactive and patient-centric healthcare models, connecting and empowering stakeholders across the spectrum; from home to acute-care settings at key touch-points throughout our lifespan.

The dominant element of Connected Health is the acquisition of health-related data from the patient in the appropriate context and using aggregation and communication infrastructures to analyse and distribute it amongst the relevant stakeholders at appropriate times. Data may comprise objective results from standard biomedical tests, subjective reports of symptoms or feelings, or on-going monitoring of health-related behaviours in the home and community using body-worn or ambient sensor networks. Data are subsequently aggregated, stored, shared and analysed to derive actionable information triggering appropriate interventions in a proactive manner. A key feature of Connected Health is the potential to bring the patient into the management of their own care, through timely provision of relevant, health- related information and feedback.

To address the challenge the Action will pursue three key objectives, which are described below.

## **Objective 1 - Input for future market applications (including cooperation with private enterprise)**

Addressing stakeholder concerns will require an increase in the knowledge-base in the following key areas:

- The integration of technical and process innovation: how component technologies can be used to improve health outcomes; how contextual factors influence the impact of care models; the cost savings associated with Connected Health; adoption and implementation models and standards within a regulatory framework; and importantly, sustainable business models.
- How to shift healthcare focus from hospitals and clinics to the community and the home thus reducing costs.
- Connecting stakeholders to share administrative and clinical information in a timely fashion.

A central goal of the COST Action “ENJECT” is to buttress strategic cooperation between European research partner and develop a roadmap to maximise healthcare-delivery value-chains.

Private enterprise and public researchers are developing technological building blocks that can be used to underpin new models of healthcare, ‘connecting’ stakeholders by means of timely sharing of administrative and clinical information. The adoption of healthcare technologies is one way to decrease cost, and increase effective and flexible patient/physician exchanges.

### **State-of-the-art**

Connected Health has the potential to transform society by delivering a smarter, more efficient approach to health and social care. However, despite encouraging recent reports from large-scale, home-based implementations of Connected Health technology platforms, the evidence for its effectiveness - in terms of clinical outcomes, adoption rates and cost savings - is limited. To promote the adoption of Connected Health, concerted programmes of research and analysis must provide evidence of the fiscal viability of Connected Health to patients, citizens, medical providers, insurance companies and governments.: by estimating the costs, benefits – clinical and economic - and return-on- investment.

Connected Health may be conceptualised as part of the Key Enabling Technology (KET) movement, as many of the technologies are associated with high research and development intensity, rapid and integrated innovation cycles, and highly-skilled employment. Furthermore,

many are of systemic relevance, multidisciplinary and trans-sectorial, with potential to induce structural change. Importantly for Connected Health, KETs have two specific characteristics: they are embedded at the core of innovative products and they underpin strategic European value-chains.

### **Relevance/Timeliness**

Connected Health represents the current move in Europe towards leveraging advances in technology to deliver more efficient healthcare systems. It can underpin the innovation required at a health and social-care service level to meet current and future challenges posed by demographic changes and uncontrolled healthcare costs. Yet, in spite of the potential of Connected Health to meet these challenges, achieving a truly Connected Health and social-care ecosystem has proven challenging.

The COST Action “ENJECT” will address the difficulties in providing evidence for Connected Health models: an overemphasis on technology rather than its use to enhance existing healthcare models; insufficient clinician-led care pathway experimentation; and critically, lack of granular market and financial research identifying the avenues for optimisation of Connected Health market-share.

Connected Health systems and devices need to be driven by the requirements of end-users rather than technical capabilities. Even when technological advances have been deployed in care settings with demonstrated effect, the traditional care model has not been seriously challenged. An impediment is a reluctance among the medical establishment to adopt revolutionary innovations. This reluctance is caused by concerns over costs of adoption and fiscal viability. Finally, physicians are faced with the difficulty of utilising the data these technologies provide to make decisions about the patient’s optimal clinical pathway to ensure that preventions and treatments are efficient and effective. Thus decision- making must be enabled from both a clinical and economic perspective. The lack of compelling research evidence highlighting this practicability is troubling, creating a significant barrier to clinician, and thus market buy-in.

### **Feasibility**

Connected Health requires a group of industry partners each targeting diverse customer propositions with supporting resources, capabilities and diverse economic logics. This specialisation of expertise is a strong and enduring feature of today’s healthcare markets. For market-focused value delivery in Connected Health, specialised value-chains need to be unified into networked solutions that are

modular in their setup, highly customizable in deployment, delivering sustainable value to each firm and player. One central challenge is the development of models enabling stakeholders to innovate together and provide evidence to persuade healthcare providers to invest in Connected Health.

The business modelling challenge is to create a collaborative business model enabling industry partners to identify, create value for, and capture economic returns from customers in specific healthcare ecosystems. Collaborative business models can be defined in network terms as the description of the roles of various network actors and the flows between the actors of product, service, information and revenue. Customer and patient expectations in this market are highly dynamic so business models need continuous adaptation to deliver on changing expectations. Micro- and macro- level assessment across markets will deliver a reliable knowledge-base on patient expectancies, preferences, and attitudes towards Connected Health, technological use, and payment models in healthcare.

The economic challenge lies in a fundamental change in the financing of patient care models and the regulatory frameworks underpinning it. Along with the lack of a comprehensive data knowledge-base, this, rather than physician or patient reluctance, remains the biggest challenge to implementation of Connected Health. The lack of an international standard framework critically hampers the future of Connected Health. To identify best-practice an international approach is required to establish information types and formats, systems and medical devices, information managed procedures to provide effective and efficient care, and the clinical pathways within which this information will be used. Transnational research and collaboration is essential to provide this standard framework, from which variability in physician/health-care can be reduced.

Underpinning economic and business model domains is a thorough understanding of citizen, health-care provider, caregiver and patient needs, attitudes, behaviours and perceptions - for individual applications as well as compared across markets and national boundaries.

<b>Risk Assessment</b>	<b>Solution</b>
Action Members do not complete audit or assessment frameworks	Ensure templates are clear with minimum free text. Circulate early.
Models and systems are too disparate to enable comparison.	Focus on key common and differentiating factors.

## **Objective 2 – Comparison and/or performance assessment of models, technologies, and methodologies**

### **State of the Art**

There are many excellent examples of innovation in Connected Health at a technological, process or business model level internationally. For example, the connected chronic disease management programmes that are in force in the Danish healthcare system and the TF3 pilot programme that is being rolled out in northern Ireland at present to provide a Remote Telemonitoring Service.

However, these exist as small ‘islands’ and are not being sufficiently leveraged as best practice exemplars for other jurisdictions. In order for researchers, industry, the medical establishment, and government to justify and advocate further investment in Connected Health, comparisons must be made between Connected Health and traditional healthcare models in different jurisdictions across a range of different essential criteria, such as healthcare revenue modelling, technologies used to improve outcomes, and methodologies used to assess Connected Health.

### **Relevance/Timeliness**

Lack of a European platform for comparison of approaches to, experiences gained from, and performance of innovations in Connected Health is resulting in duplication of effort, with consequent underutilisation of scarce R&I resources. We cannot afford the financial implications and time inefficiencies associated with this duplication.

### **Models**

Comparisons must be made between current clinical care pathways and putative Connected Health pathway models, through rigorous identification and inclusion of costs of activities related to healthcare conditions, as they progress along a care pathway.

Using dementia-care as an exemplar, time-driven activity-based costing could be conducted for both traditional and Connected Health pathways, to identify and model all relevant cost-drivers in this pathway. In doing so areas of administrative streamlining, clinical repetition, and patient adherence can be identified in a timely manner, thereby reducing patient costs, and more long-term economic and clinical costs related to untreated or unidentified healthcare issues.

### **Technologies**

In order for Connected Health to meet patient and healthcare ecosystem needs it is necessary to foster competition - between companies developing products for similar health solutions, and

between companies developing unrelated products but through which market share can be captured. To facilitate competition, and thus increase the standard of offerings from technology companies, comparisons must be conducted by third-party researchers and organisations that possess the technical and data-analytic expertise to assess differential advantages among a range of competing products. Fundamental to this is the design and implementation of studies to assess the performance of competing electronic applications designed to reduce specific dementia-related cognitive decline as an initial illustration.

A fluid database and system of disease-specific and appropriate technologies can be maintained and updated, thereby creating a patient-centric Connected Health system. Involvement of a variety of international researchers and research bodies is critical to ensure clarity of study design and de-duplication of Connected Health research, and minimise any potential for researcher bias, and favouring of certain technological solutions.

### **Methodologies**

International cooperation and expertise is critical for the development and maintenance of a unified methodological approach to innovation and data/information repository for those involved with the Connected Health sector. By developing an internationally recognised and shared procedural standard for the way in which Connected Health studies can and should be designed and conducted - in addition to identifying and minimising duplicitous data collection, and finally, by resolving to utilise cutting-edge data analytic techniques - the process toward the development and maintenance of a genuinely Connected Health ecosystem can be placed on a solid scientific footing.

<b>Risk Assessment</b>	<b>Solution</b>
Action Members do not complete audit or assessment frameworks	Ensure templates are clear with minimum free text. Circulate early.
Models and systems are too disparate to enable comparison – lack of standard international framework	Focus on key common and differentiating factors.
Performance assessment is too limited to provide useful output	Ensure wide representation from industry and geographically at symposium and create opportunities to input.

### **Objective 3 – Bridging separate fields of science/disciplines to achieve breakthroughs that require an interdisciplinary approach.**

#### **State of the Art**

As highlighted in recent studies and reports, a number of important recommendations must be addressed to deliver a truly Connected Healthcare model: these include clinical needs, technologies, implementation models and care pathways, human and organisational factors, provision of evidence regarding clinical and economic efficacy, analytics, and commercial concerns. Addressing these issues is only possible through an interdisciplinary approach, and ENJECT will be a “Beacon Group” to facilitate this.

#### **Relevance/Timeliness**

Recent advances in healthcare technologies must navigate a ‘Valley-of-Death’ - a chasm between discoveries in life sciences and their translation into safer, more effective therapies. Whilst firms develop and exploit their technologies, they often pay less attention to the customer’s problems. This results in fragmented, incomplete systems, lacking efficient value-chains from technology to solution. An opportunity exists whereby Connected Health, and well-placed groups like the COST Action “ENJECT”, can provide the overview and clarity to facilitate the transition from research and development to the market place.

Connected Health has not yet achieved widespread adoption across Europe. Primary reasons include its fragmentation: the lack of evidence regarding the clinical and cost-effectiveness of Connected Health solutions; the Valley-of-Death; and a lack of knowledge as to Connected Health business and revenue-models. Evidence for Connected Health effectiveness requires companies, clinicians, patients and carers, using an international perspective, to innovate at a service or care-pathway level, thereby augmenting our understanding of the factors which impact on the potential success of Connected Health solutions. This Action will bring together business, science and technology communities across Europe to address the commercial development of this sector.

#### **Feasibility**

The COST Action “ENJECT” will bring together business modellers, market analysts, clinicians, technologists, engineers, economists, ethnographers and other health researchers to help society answer: How to connect patients and care-givers with appropriate and sufficient therapies to deliver optimal health results in an era of stretched resources and increasing demands?

Academic researchers, clinicians, policy-makers, payors and industry all approach this evidence-gap from different perspectives. Addressing this shortfall in our knowledge, and unlocking the potential offered by Connected Health requires a truly multidisciplinary approach. It is not possible for one sector to solve the multifaceted challenge of providing the evidence and knowledge that will drive adoption. Therefore, this Action will bring together international experts from different sectors, to share data, knowledge and experiences, enabling the provisions of information about their discrete needs and constraints in advancing the field, thereby producing a more efficient approach to research and innovation in Connected Health.

For example, those involved in the technology and business fields need greater understanding of the precise nature of the unmet clinical need, whereas clinicians need greater understanding about business and revenue models that might enable industry to sustain involvement in the space. Until now, researchers in different sectors have not collaborated sufficiently within Connected Health, exposing themselves to examples of technological developments that do not truly meet clinical needs nor lend themselves to implementation on the ground within the context of a sustainable commercial proposition.

Without a convergence platform for transfer of knowledge across sectors, Connected Health will continue to be characterised by discrete silos of activity in different sectors.

Risk Assessment	Solution
Difficulty in attracting certain representative groups (e.g. clinicians/policy makers)	Minimise required time for such groups. Ensure value of outputs is clearly communicated.
Integrating researchers and research groups in relevant areas but not currently focused on Connected Health research	Ensure broad communications and invitation campaign in each domain area regardless of Connected Health outputs to date.

**Scientific, technological, and societal impact of solving these problems**

**Scientific Impact:**

Research focuses on developing data analytics techniques and tools to efficiently store, manage and extract valuable information from medical data. Techniques will be developed to help understand

the predictive value of data, which are dynamic, heterogeneous and complex. ENJECT will not simply function as a network for assessing data, but will actively engage in the high-level intellectual transfer of information.

### **Technological Impact:**

No individual technology or service provider can provide an integrated Connected Health-solution. The combination of sensors, aggregation/ communication/ storage/ analytics-infrastructure, assistive devices, and support packages required for a given clinical management scenario must come from multiple providers and requires input from multiple international stakeholders.

This Action will bring together experts across a range of disciplines throughout Europe, and through them access a diverse and representative knowledge-base, including care-system providers, private companies, regulators and policy makers. The potential to bring together the technological building blocks and knowledge necessary for a successful Connected Health solution, in the context of a joined-up regulatory approach and robust, internationally applicable business modelling and market analysis presents a unique and exciting opportunity.

Technologies can be trialled, linked, tested and controlled across boundaries and in the most complete context possible. Gaps will be identified that create opportunities for new technological development. In tandem, communication across disciplines and systems will reduce the need for technological duplication allowing researchers and developers alike to focus on ensuring that the technology works in practice.

### **Societal Impact:**

In the future Connected Health ecosystem this Action envisages services incorporating applications in mobile-, electronic-, wireless- and tele-health are firmly patient-centric; delivering a proactive healthcare model, which enables patients to engage fully in management of their health, and identifies problems early, which enable timely interventions, reduces overall healthcare costs and results in optimal healthcare outcomes.

A Connected Health system offers potential for improved health outcomes for hospital-based patients, but critically is a low-risk way to reduce the danger of inappropriate hospitalisation for many; by offering a higher level of care and better quality of life for those who can avail of less invasive or home-based health solutions offered in such a system. Connected Health will deliver an

economically efficient healthcare model, allowing societies and governments to leverage technological advances, thus responding to demographic shifts.

A key objective of Connected Health is to shift current healthcare focus from hospital and clinics, into the community and home; a paradigm-shift from a curative to a preventative healthcare model. A paradigm-shift of this nature holds the potential to reduce hospitalisation and thus primary clinical and financial healthcare costs.

## **B. ADDED VALUE OF NETWORKING**

Networking is key to the development, and ultimately the delivery of Connected Health solutions. Research networks and implementation networks must be inter-disciplinary and cross-border to:

- Design appropriate solutions that will integrate with existing elements and stakeholders
- Partner well to offer a full solution; and
- Help set the rules facilitating industry wider interoperability

Europe is a dominant market for the use of Connected Health in home care service, in part due to the high availability of telephone and Internet services. Europe has about 260 million people connected to land lines, more than 300 million cell phone users and 230 million Internet users.

Recent studies have predicted 5 billion mobile phone users by 2017.- However, adoption of a truly connected and integrated health system across Europe has not occurred on a widespread basis. One of the primary reasons for this is a lack of collaboration and integration amongst the stakeholders involved in the management of health and social care, from frontline health and social care workers, to technologists, policy makers, payers and business leaders. This network will provide a platform for cross-sectorial and regional exchange of ideas, expertise, data, and experiences to enable progress in this field.

IBM research, on the future of connected health devices at the IBM Institute for Business Value conducted an interview of medical device makers and consumer electronics companies as well as input from more than 1,300 current device users and caregivers. This interview reveals insights about targeting Information Seekers. To capture the emerging market of Connected Health, four principles need to be considered: 1) Ease of adoption by consumers, 2) Design the solution with the end result in mind. This involves integration with multiple stakeholders. 3) Pick a position and

partner well as it is unlikely any single institute will be able to offer a full solution. 4) Help set the rules facilitating industry wide interoperability. IBM's findings emphasize the need for extensive partnering across the electronics, healthcare and life sciences industries. The building blocks of a health device ecosystem are rapidly emerging, with market adoption and innovative progress across mobile devices, home-based devices, web-based resources, electronic health records and personal health records. This COST Action brings together experts, with a particular focus on early stage researchers, from a number of disciplines to enhance the opportunity for shared learning to emerge from existing activities. Furthermore, the quality of the research will benefit to a great extent from such a network.

### **How networking activities would help meet the challenge by leveraging nationally- and institutionally- funded resources?**

A number of European framework projects have involved European academic institutions delivering complex pan-European-focused efforts in Connected Health, yet these projects are not yet networked effectively, nor are they always integrating different sectors (technical/clinical /business /policy). For example, one of these projects involved development of an innovative tele-monitoring system for elderly users with wearable and ambient sensors. In addition to the monitoring function, the system provides the elderly user with a means of communication with peers, family, health professionals and caretakers. Another aims to deliver a cost-effective, proactive management service for patients with chronic diseases, like diabetes, through remote monitoring. The technology developed facilitated communication across groups of users using different wireless standards in addition to addressing the problem of how the interaction between humans and embedded systems can be efficiently supported.

This COST Action brings together high-profile experts across a range of disciplines and geographies and through them accesses a diverse and representative knowledge base including care system providers, private companies, regulators and policy makers. The potential to bring together the technology building blocks and knowledge necessary for a successful connected health solution, in the context of a joined up regulatory approach and robust, internationally applicable business modelling and market analysis, and to use this to inform policy, presents a unique opportunity.

Through this COST Action, networking between a number of participants in national and European research projects will be established. This will stimulate collaborative research with enhanced impact due to the benefit derived from sharing experience and data.

The network already includes representatives from industry-led national research programmes in the areas of Connected Health, as well as subject matter programmes such as data analytics that boast substantial industry funding and support. Such research programmes will benefit from and contribute to ENJECT, integrating Connected Health technology and solution providers into the research network. This not creates successful research partnerships and ultimately leads to profitable business partnerships.

The Action will aim to address in a timely and effective manner five key criteria for successful Health IT: 1) money, 2) technological capability, 3) credibility, 4) timing, and 5) cooperation/standardisation. This COST Action will overcome these challenges by bringing experts from European and International Partner Countries (IPCs) together under four Working Groups (WGs):

WG 1) Economics and Impact;

WG 2) Technology Assessment;

WG 3) Standards of Care;

WG 4) Business and Revenue Models.

Members from different disciplines and different backgrounds (academic/industry/policy) will be represented on each Working Group and Working Groups will lead and collaborate on different elements of the Action ensuring cross pollination and thus delivering on the Action objectives.

The COST Action ENJECT will create a unique alliance between health, business, technology and policy sectors across Europe and beyond.

### **WG 1: Economics and Impact**

The Economics and Impact working group is focused on the challenge of fundamental change in the construct and financing of the patient care model and in the regulatory frameworks that underpin it. This group will address the lack of a comprehensive data knowledge-base that captures economic returns from customers in specific healthcare ecosystems - a significant challenge to widespread implementation of connected health. It will do this by developing an assessment framework for MS

healthcare models, collating these assessments into a comprehensive overview of healthcare systems in Europe and publishing from this a comparison of European healthcare systems and associated potential Connected Health models and technologies to enable private enterprise to better plan and market connected health technologies.

In order to address stakeholder concerns within the Connected Health domain, an increase in the knowledge-base in the following key areas is needed: contextual factors influencing the impact of care models; the cost savings associated with connected health solutions; adoption and implementation models, connected health economy model, and standards within a regulatory framework; and importantly for the sustainability of a connected health ecosystem, commercial exploitation models that are economically, socially and environmentally sustainable.

To address this Working Group 1 will organise a symposium illustrated by the sample performance assessments of both connected health business models and connected health technologies. These will be attended by academics, policy makers/regulators and private enterprise.

This Working Group brings together field experts from each of these key areas as well as experts from the healthcare domain to develop a strong, world class network of health economists. This Working Group will contribute towards the Action objectives by giving access to various care models, connected health solutions, implementation models and regulatory frameworks. The alliance between these experts will not be achievable with the same quality and scope without the COST Action support.

## **WG 2: Technology Assessment**

WG2 will aim to bring consistency of approach to technology assessment in the context of Connected Health in Europe as individual technology or service provider investment in the development of technological building blocks, market research and test deployments has failed to provide an integrated Connected Health solution. The combination of sensors, aggregation/communication/storage infrastructure, analytics, assistive devices, and support packages required for a clinical management scenario must come from multiple providers and requires input from multiple transnational stakeholders.

WG 2 will lead an audit of complete, ongoing, or planned Connected Health research projects and programmes with a view to avoiding redundancy and ensuring state-of-the-art research. This will

extend to all Connected Health research areas such as electronic health, digital health, tele health and monitoring, disease management, and home based care. This Working Group will also ensure sharing of published and unpublished knowledge, data and experiences as to how each subject field can deliver on a Connected Health research agenda. WG2 will ensure that this audit and sharing will extend to community interest companies and not for profit initiatives that are influential in the area of Connected Health globally.

This Working Group forms a network of experts from diverse backgrounds, with significant fundamental and translational research contributions to the areas of medical informatics, health IT, medical devices, clinical innovation, human factors, and business modelling. Bringing this network of expertise together will provide a valuable resource in terms of exchange of knowledge regarding the process of technology enabled innovation in health management. Furthermore, there is much to be learned from networking around the multiple approaches to evaluation of the impact of healthcare technology infrastructures and supports.

Thus, this Working Group will contribute towards the Action objectives by facilitating communication across disciplines and systems to reduce the need for technological duplication allowing researchers and developers alike to focus on ensuring that the technology works in practice. In tandem, technologies can be trialled, linked, tested and controlled across boundaries and in the most complete context possible. Gaps will be identified that create opportunities for new technology development.

### **WG 3: Standards of Care**

WG 3 will lead specific targeted missions to investigate in detail a maximum of three healthcare markets and associated Connected Health models or potential models and will contribute to performance assessment and academic protocol development from a standards of care perspective. WG3 will ensure that standards of care form the basis of Connected Health and that care pathways shape the standards of care. Such knowledge intensive work differs from routine work in that actors may perform knowledge intensive actions in different ways, depending on their intuition, preferences, and expertise.

The similarities between the health and software domains are to be exploited to model the care pathways (using process modelling techniques) and information required by a variety of stakeholders in the connected health network. This Working Group provides for the adoption of

process modelling techniques originally developed for use in software, and also for applying them to the health domain and will support potential partners from associated backgrounds to shape a very robust network in the domain of standards of care.

This WG requires the development of prototypes to understand how best process models can be presented to healthcare professionals. This Working Group will contribute towards the Action objectives by enabling experts who have knowledge and experience of prototyping tools and system environments to promote communication and develop the best process model.

#### **WG 4: Business and Revenue Models**

WG4 is responsible for the development of an improved model of technology innovation in the area of CH as two or more different views and approaches to the same Connected Health issues come together to bridge the so called “Valley of Death” gap.

Research on business and revenue models, in particular sustainable business models design and implementation for new technologies, is relatively new in business research. There was research on dot-com business models in the late 1990s, but the real focus on this area since has been a series of special issues on the topic and creation of new business model research communities of practice, particularly in Europe, have fuelled research in the field. Business model research networks are diffuse across Europe and multi-disciplinary in nature. This Working Group will establish and deepens network connections between these researchers and leverage inter- disciplinary business model research centres in countries across Europe with large interdisciplinary research teams within (but less so across) European countries, exploring business model design. A common theme for these research centres is supporting a mix of small and mid-sized entrepreneurial firms that have new technologies, but lack a business model to scale these technologies into multi-disciplinary solutions that customers want, with large firms that have scale in exploitation and are looking for partners to connect new technologies to solutions.

This Working Group will contribute towards the Action objectives by bringing together expert networks so that they can share their insights on business model design in areas including the digital economy, bio and nanosciences, digitalisation for consumers and consumption, information technology and healthcare, with the goal of supporting the development of sustainable and often collaborative business models in the emerging connected health sector. As many of these research centres are already interdisciplinary in nature, combining technologists, healthcare and business

researchers together, they are well placed to network in our trans-disciplinary Connected Health community and thus envisage how the network can create and implement a research agenda to support this sector.

**C. MILESTONES AND DELIVERABLES: CONTENTS AND TIME FRAMES STRATEGY**

**Objective 1 (A.4) - Type: Comparison and/or performance assessment of theory/model/ scenario/projection/simulation/narrative/methodology/technology/technique**

1. Stakeholders Outreach, including Unwritten Inputs and Dissemination, to end users/practitioners.
2. Contacts with Stakeholders, Delivery of Written Input Necessary for Future Market Exploitation to Business Enterprises.
3. Science and Technology Event or Meeting, Training School.

**Objective 2 (A.8) - Type: Input for future market applications (including cooperation with private enterprises)**

1. Documents to be Used as Input to Stakeholders, to users/practitioners.
2. Action Science and Technology Meeting, Short Term Scientific Missions Committee.
3. Science and Technology Coordination, Short-Term Scientific Missions (STSM).

**Objective 3 (B.13) - Type: Bridging separate fields of science/disciplines to achieve breakthroughs that require an interdisciplinary approach**

1. Unpublished Aspects of Knowledge Creation, Including Experimentation and Testing, other.
2. Internal and External Communication, Website.
3. Science and Technology Event or Meeting, Action Conference.

The milestones and deliverables of the objectives stated above are envisaged as follows:

Objective	
1 (A.4)	<p>Input for Future Market Applications (including cooperation with private enterprise)</p> <p>A central goal of ENJECT is to facilitate technological innovation and buttress</p>

	<p>strategic cooperation between its European research partners in order to develop a roadmap towards the maximisation of healthcare-delivery value-chains.</p> <p>The lack of an international standard framework from an implementation perspective critically hampers the future and widespread development of Connected Health. In order to identify best practice for implementation of clinical pathways based on Connected Health solutions, an international approach is required that can establish the information types and formats, systems and medical devices, information managed procedures to provide effective and efficient care, and the clinical pathways within which this information will be used. Transnational research and collaboration is essential to provide this standard framework, from which variability in physician/health-care can be reduced.</p>		
<b>Milestones</b>			
M 1.1	1 <sup>st</sup> MC (“Kick off”) meeting		
M 1.2	Parameters for systems comparison agreed		
M 1.3	Published comparison of systems on website, electronic distribution to lined enterprise, policy makers and academic institutions		
M 1.4	Subjects for case studies (STSMs) agreed		
M 1.5	STSMs completed		
<b>Deliverables</b>		<b>Who?</b>	<b>Time</b>
D 1.1.1	An audit of complete, ongoing or planned Connected Health research projects and programmes with a view to avoiding redundancy and ensuring state-of-the-art research	Led by WG 2 Input from all members	M 4-12
D 1.1.2	A summary of the current state of Connected Health research	WG 2	M 12
D 1.2.1	Development of an assessment framework for MS healthcare models including elements such as : - Payment models - Delivery models - Level of connected health implementation - Key healthcare statistics	Led by WG 1 Input from all members	M 8

	- Key communications statistics - Technologies available		
D 1.2.2	Completion of said assessment by a representative COST member for each participating MS	All members	M 12
D 1.2.3	Working Group analysis and discussion of information	WGs 2 & 4	M 18
D 1.2.4	Collation of assessments into a comprehensive overview of healthcare systems in Europe	WG 1	M 22
D 1.2.5	A published Comparison of European healthcare systems and associated potential Connected Health models and technologies to enable private enterprise to better plan and market connected health technologies	WG 1	M 24
D 1.3.1	Specific targeted missions to investigate in detail a maximum of three healthcare markets and associated connected health models or potential models	Selected Member [Co-ordinated by WG 3]	M 12 – 36
D 1.3.2	In depth exploration of a maximum of three healthcare models through STSMs	Selected Members	M 36
<b>Objective</b>			
2 (A. 8)	<p>Comparison and/or performance assessment of theory/model/scenario/projection/simulation/narrative/methodology/technology/technique)</p> <p>In order for researchers, technology companies, physicians and other stakeholders (particularly policy-makers and the medical establishment) to advocate for further investment in Connected Health, comparative studies must be undertaken between Connected Health and traditional healthcare models. These should cover different jurisdictions across a range of different essential criteria, such as healthcare revenue modelling, technologies to improve outcomes, and methodologies used to assess Connected Health.</p>		
<b>Milestones</b>			
M 2.1	1 <sup>st</sup> MC (“Kick off”) meeting		

M 2.2	Parameters for systems comparison agreed		
M 2.3	Published comparison of systems		
M 2.4	Subjects for case studies (STSMs) agreed		
M 2.5	Symposium - European Healthcare Systems in the Context of Connected Health		
<b>Deliverables</b>		<b>Who?</b>	<b>Time</b>
<b>D1.2.1</b>	Development of an assessment framework for MS healthcare models including elements such as: - Payment models - Delivery models - Level of connected health implementation - Key healthcare statistics - Key communications statistics - Technologies available	<b>Led by WG 1</b> <b>Input from all members</b>	<b>M8</b>
D 2.1.2	Completion of said assessment by a representative COST member for each participating MS	All members	M 12
D 2.1.3	Working Group analysis and discussion of information	WGs 2 & 4	M 18
D 2.1.4	Comparison of European healthcare systems and associated potential Connected Health models and technologies	WG 1	M24
D 2.1.1	Technical and editorial development of a website. Encouraging populating of information dissemination elements of website	MC  All members	M 8
D 2.2.2	Action Website to act as forum for dissemination of the information to the wider public on the synthesised findings/learnings from the Action	MC	M 8
D 2.3.1	Performance assessment of sample (<5) of connected health business models	Led by WG 1. Input from all WGs	M 32
D 2.3.2	Performance assessment of sample (<5) of connected health technologies	Led by WG 1. Input from all WGs	M 40
D 2.3.3	Symposium illustrated by the sample performance	WG 1	M 42

	assessments of both connected health business models and connected health technologies. These will be attended by academics, policy makers/regulators and private enterprise		
<b>Objective</b>			
3(B.13)	<p>Bridging separate fields of science/disciplines to achieve breakthroughs that require an interdisciplinary approach</p> <p>Providing evidence for the effectiveness of Connected Health requires that companies, clinicians, patients and carers' voices are brought together, using an international perspective, to innovate at a service or care-pathway level, thereby augmenting our understanding of the multiple factors which impact on the potential success of Connected Health solutions. There are lessons for the development of Connected Health, and this COST Action will bring together business model, and science and technology communities across the EU to address the commercial development of this sector.</p> <p>Whilst firms develop and seek to exploit their own Connected Health technology, they often pay less attention to the crucial problems of the customer, who is located within a solutions ecosystem. This can result in fragmented and incomplete systems, wherein few if any industry members can manage an efficient value chain, from technology to solution. Thus a tremendous opportunity exists whereby Connected Health, and well-placed groups like ENJECT, can provide much needed clarity and the overview essential to facilitate and guide in the transition from research and development, to the marketplace and patient.</p>		
<b>Milestones</b>			
M 3.1	1 <sup>st</sup> MC ("Kick off") meeting		
M 3.2	Action Conference		
M 3.3	Symposium - European Healthcare Systems in the Context of Connected Health		
M 3.4	Idea generation workshop		
M 3.5	Funding proposals generated and submitted		

<b>Deliverables</b>		<b>Who?</b>	<b>Time</b>
D 3.1.1	Website inviting contact and clearly outlining the purpose of the Action Ensure broad dissemination Public relations campaign to include traditional, social and trade media	MC	M 1-20
D 3.1.2	Ensure diverse membership including: business and revenue modellers, clinicians, technologists, engineers, economists, ethnographers and health researchers from a wide range of countries. Ensure representation from policy makers, regulators and private enterprise.	MC	M 20
D 3.2.1	Share published and unpublished knowledge, data and experiences as to how each subject field can deliver on a Connected Health research agenda	WG 2 All Members	M 1-48
D 3.2.2	Make relevant introductions to a wide variety of European Health Systems (policy makers) and their associated Connected Health models (or lack thereof).	All Members	M 1-24
D 3.3.3	An improved model of technology innovation in the area of CH as two or more different views and approaches to the same Connected Health issues come together to bridge the so called “Valley of Death” gap	WG 4	M 36
D 3.3.1	Performance assessment of a sample (<5) of connected health business models	Led by WG 1 Input from all WGs	M 32
D 3.3.2	Performance assessment of sample (<5) of abovementioned connected health technologies	Led by WG 1 Input from all WGs	M 40
D 3.3.3	Symposium (training school) illustrated by the sample performance assessments of both connected health business models and connected	WG 1	M 42

	health technologies. These will be attended by academics, policy makers/regulators and private enterprise		
D 3.4.1	Idea Generation Workshops as part of action meetings supported by funding experts from member universities	All Members (led by MC)	M 6, 18, 30, 42
D 3.4.2	Proposal teams formed and proposals generated	All Members	M 48
D 3.4.1	Technical and editorial development of a website. Encouraging populating of information dissemination elements of website.	MC  All members	M 20
D 3.4.2	Action Website to act as repository for cross-national information on the field of CH. Bridging the gap between the different fields and countries of study	MC	M 24
D 3.5.1	Development of an academic protocol for Connected Health studies across both disciplinary and geographical boundaries	MC All WGs All Members	M 36
D 3.5.2	Shared procedural standard for Connected Health studies	MC	M 42

## **D. ACTION STRUCTURE AND PARTICIPATION – WORKING GROUPS, MANAGEMENT, INTERNAL PROCEDURES**

### **Management Committee**

ENJECT will be managed by a Management Committee (MC), nominated by the COST Countries National Coordinators. The Management Committee will be the decision-making body for the COST Action ENJECT and each participating COST Country will have voting rights.

Experts from approved International Partner Countries and Near Neighbour Countries will be represented at Management Committee level by non-voting Management Committee Observers who will observe decision making and contribute to related discussions.

Among others, the Management Committee will: i) coordinate the organisation of annual ENJECT meetings and workshops; ii) ensure information flow and link activities to other Actions and EU programmes; iii) decide on Short Term Scientific Mission support; iv) prepare intermediate and final reports; v) ensure dissemination of this COST Action outcomes on an ongoing basis.

The Management Committee will be supported in its work by a Core Group comprising:

- The Action Chair
- Action Co-Chair
- Working Group Leaders
- Short Term Scientific Mission Manager
- Dissemination Manager

### **Working Groups:**

The ENJECT Action will be structured into four Working Groups to deliver on ENJECT's objectives:

- Working Group 1: Economics and Impact
- Working Group 2: Technology Assessment
- Working Group 3: Standards of Care
- Working Group 4: Business and Revenue Models

Working Groups will be led by an expert in that specific field but will contain members from all disciplines ensuring an interdisciplinary approach. Membership of the Working Groups will take into account:

- Geographic distribution
- Complementarity to other Working Group members
- Age and gender distribution

Working Groups will lead one or more tasks within the COST Action and contribute to tasks led by another Working Group. Joint Working group meetings and output sessions will coincide with COST Action MC meetings or workshops wherever possible to ensure both efficient use of Action resources, and to encourage cross pollination between working groups.

Individual WG members will contribute early in this COST Action. They will be individually responsible for discrete elements of specific tasks as well as being encouraged to contribute to thought leadership and informed debate.

In addition to a wide range of regular participants from academia, industry and policy-making, occasional participants (industry and academic experts) will be invited on an ad hoc basis to events where their input can inform the progression of the ENJECT agenda or where they are valuable in the dissemination of this COST Action outcomes.

<b>Timing</b>	<b>Activity</b>	<b>Role</b>	<b>Output</b>
<b>Management Committee Responsibilities</b>			
M 1-6	Appoint Chair, Vice-Chair and WG Leaders (1 <sup>st</sup> MC Meeting), solicit applications for WG membership	Leader	Structure
M 8	Development of website. Encouraging populating of information dissemination elements of website	Leader	Deliverable
M 1-20	Membership Campaign	Leader	Deliverable
M 36	Development of an academic protocol for Connected Health studies	Leader, Manager	Deliverable
<b>Working Group 1 Responsibilities</b>			
M 8	Development of an assessment framework for MS healthcare models	Leader	Deliverable
M 22	Collation of assessments into a comprehensive overview of healthcare systems in Europe	Leader	Deliverable
M 24	Comparison of European healthcare systems and associated potential Connected Health models and technologies	Leader	Deliverable
M 32	Performance assessment of a sample (<5) of connected health business models	Leader	Deliverable
M 36	Development of an academic protocol for Connected Health studies	Contributor (led by MC)	Deliverable
M 40	Performance assessment of sample (<5) of connected health technologies	Leader	Deliverable
M 42	Symposium illustrated by the sample performance	Leader	Deliverable

	assessments of both connected health business models and connected health technologies. Attended by academics, policy makers/regulators and private enterprise		
<b>Working Group 2 Responsibilities</b>			
M 4-12	An audit of complete, ongoing , or planned Connected Health research projects and programmes with a view to avoiding redundancy and ensuring state-of-the-art research	Leader	Deliverable
M 1-48	Share published and unpublished knowledge, data and experiences as to how each subject field can deliver on a Connected Health research agenda	Leader	Deliverable
M 32	Performance assessment of a sample (<5) of connected health business models	Contributor	Deliverable
M 36	Development of an academic protocol for Connected Health studies across both disciplinary and geographical boundaries	Contributor	Deliverable
M 40	Performance assessment of sample (<5) of connected health technologies	Contributor	Deliverable
<b>Working Group 3 Responsibilities</b>			
M 12 - 36	Specific targeted missions to investigate in detail a maximum of three healthcare markets and associated connected health models or potential models.	Leader	Deliverable
M 32	Performance assessment of a sample (<5) of connected health business models	Contributor	Deliverable
M 36	Development of an academic protocol for Connected Health studies across both disciplinary and geographical boundaries	Contributor	Deliverable
M 40	Performance assessment of sample (<5) of connected health technologies	Contributor	Deliverable
<b>Working Group 4 Responsibilities</b>			
M 32	Performance assessment of a sample (<5) of	Contributor	Deliverable

	connected health business models		
M 36	An improved model of technology innovation in the area of CH	Leader	Deliverable
M 36	Development of an academic protocol for Connected Health studies	Contributor	Deliverable
M 40	Performance assessment of sample (<5) of connected health technologies	Contributor	Deliverable
<b>Members Responsibilities</b>			
M 1-24	Make relevant introductions to a wide variety of European Health Systems (policy makers)	Individually responsible	Deliverable
M 1-48	Share published and unpublished knowledge, data and experiences	Contributor	Deliverable
M 6, 18, 30, 42	Idea Generation Workshops	Contributor	Deliverable
M 12	Completion of healthcare model assessment for own MS	Individually responsible	Deliverable
M 20	Populating of information and dissemination elements of website.	Contributor	Deliverable
M 36	Development of an academic protocol for Connected Health studies	Contributor	Deliverable
M 36	In depth exploration of a maximum of three healthcare models through STSMs	Individually responsible	Deliverable
M 48	Proposal teams formed and proposals generated	Individually responsible	Deliverable

### Timetable

This Action will last 4 years and will be organised according to the timetable below. During the first six months a group of focused and mutually complementary experts from the relevant sectors will be invited to join all Working Groups. Thereafter, the MC will meet once a year, the WGs will meet at least once a year and Idea Workshops will be also organised once a year. STSMs will be organised to assess healthcare models and markets.

1 <sup>st</sup> MC (“Kick off”) meeting	M1
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2nd MC meeting and joint WG Meeting to assess direction of WG activities	M4
STSMs (Healthcare models and markets)	M4-48
Action workshop 3rd MC meeting, evaluate and tailor direction/composition of WGs	M18
1 <sup>st</sup> Mid-term Report	M24
Action workshop 4th MC meeting	M 30
Idea Generation Workshops	M 6, 18, 30, 42
5 <sup>th</sup> MC meeting Final Action Conference "A Harmonised Approach to Global CH Innovation",	M 48
2 <sup>nd</sup> Mid-term Report	M 48
Final Report	M 48