Abstract

This document describes the general system architectures defined for the United4Health European Project which hopes to demonstrate the ‘normalization’ of the provision of remote monitoring in the continuum of care for the management of the chronic diseases of congestive heart failure, diabetes and chronic obstructive pulmonary disease. Each pilot site’s specific implementation of the service architectures is also described. Moreover, the status of the remote monitoring industry is discussed along with the use of standards-based systems.

Key Word List

Standards
Executive Summary

This report provides the initial status of the United4Health project from a technical and industry viewpoint. It describes the United4Health pilot technical architecture, equipment and standards currently in use, as well as the industry status as of December 2013.

The initial technical analysis of the United4Health pilot projects yielded a number of findings of relevance to the project related to the standards situation, the industry offers, and the state of the field overall:

- Most data transmissions followed standardised electronic network protocols, whereas messaging and data formats were proprietary. The use of web portals and secure data transmission via web protocols was more prevalent. There were two interface points for healthcare providers to integrate the telemonitoring data: at the output of the home gateway, or at the output of the telehealth aggregation / analysis centre. The home technical kit and gateway are generally outsourced to local regional telehealth providers. This is different from the Renewing Health project, one of the forerunners to United4health, in which the device integration to the gateway was in many cases done by the healthcare provider. Some data is still transmitted by manual data entry, especially for devices which are patient owned, usually glucometers and weight scales. The use of Bluetooth for a wireless connection between the physiological monitoring devices and the gateway to the long-range transmission network was seen in over 80% of the solutions used by the pilot sites. In addition, the use of mobile devices as a gateway was used in over 50% of the pilot site solutions. Moreover, each pilot site was grappling with the integration of the remotely acquired monitoring data into their existing healthcare electronic healthcare record, specifically in the areas of data privacy and access.

- There were a few standards-compliant products on the market when the project began. Many pilots used mobile and smart phones to act as data hubs; however, the implementation of standards on mobile platforms had barely begun. Continua is poised to offer mobile platform specific guidelines, and GSMA has greatly expanded their mHealth offerings and guidance to mobile network operators.

- The market for telemedicine products (in Europe and beyond) is still fragmented, often with different companies operating in different countries and different market leaders depending on the country (see Appendix B for a “state of the market”). There has been an understanding by the telehealth solution providers that the healthcare providers would like the choice of two interface points as described above (at the output of the home gateway or at the output of the telehealth centre). The customer demand for telecommunication standards and interoperability is very prevalent, and is a standard, mandatory requirement in procurements. However, customer demand for messaging and data standards is still weak, and needs to be identified in procurement documents to drive data based interoperability. At the first project meeting, a tutorial was given on how and why specifying or requiring standards at the interface between the remote monitoring service functionality and the healthcare enterprise medical record eases the ability for the data to flow between those two entities.
Change History

Version History:
0.1 2nd January 2014
0.2 4th February 2014
0.3 24th March 2014
1.0 25th March 2014

Version Changes
0.1 Initial draft
0.2 Addition of Scottish, Italian and Czech information
0.3 Editing changes due to IAT review; addition of pilot software specifics
1.0 Minor changes prior to issue

Outstanding Issues
None
# Table of Contents

## EXECUTIVE SUMMARY

## CHANGE HISTORY

## TABLE OF CONTENTS

1. **INTRODUCTION**
   
   1.1 Purpose of this document
   1.2 Glossary

2. **BACKGROUND**
   
   2.1 United4Health
   
   2.1.1 Overview and Participants
   2.1.2 Clinical Protocols
   2.2 The Industry Advisory Team

3. **THE UNITED4HEALTH PROJECT**
   
   3.1 Overview and generic technical architecture
   3.2 Czech Republic, Northwest Moravia
   3.3 Finland, South Karelia
   
   3.3.1 Blood glucose meter
   3.3.2 Mobile phone
   3.3.3 Web PHR application
   3.4 France, Nord Pas de Calais
   3.5 Germany, Berlin
   3.6 Greece, Central Greece
   3.7 Italy, Calabria
   3.8 Italy, Campania
   3.9 Norway, Northern and Southern
   
   3.9.1 Legal and Security Requirements in Norway
   3.9.2 Technical Telehealth Set-up
   3.9.3 Treatment Pathway Health Record (TPHR) and Information Integration Portal (IIP)
   3.9.4 Tablet-PC, devices and software
   3.10 Slovenia
   3.11 Spain, Basque Country
   3.12 United Kingdom, Scotland
   
   3.12.1 Scottish CHF and COPD Architectures
   3.12.2 Scottish Diabetes System Architecture
   3.13 United Kingdom, Wales

4. **SUMMARY AND ANALYSIS**
4.1 Parameters and data types collected  
4.2 Devices, interfaces, and telehealth software capabilities  
4.3 Industry  

5. CONCLUSIONS AND RECOMMENDATIONS  

APPENDIX A - REFERENCES  
APPENDIX B - STATE OF THE INDUSTRY  

TABLE OF TABLES  
Table 1: Chronic conditions by Region/Country ................................................................. 17  
Table 2: Parameters and Data Types by Chronic condition and Country .......................... 40  
Table 3: Device and Interfaces .......................................................................................... 41  
Table 4: Pilot Telehealth software capabilities for patients ............................................. 44  
Table 5: Pilot Telehealth software capabilities for clinical professional ....................... 45  
Table 6: Leading Telehealth Vendors listed by Country - 2008 ..................................... 52  
Table 7: Telehealth Vendors listed by Country - 2013 ..................................................... 52  
Table 8: Prevalent vendors by region ................................................................................ 53  
Table 9: Device Enterprise Communication ................................................................... 54  

TABLE OF FIGURES  
Figure 1: Diabetes U4H System Architecture .................................................................. 10  
Figure 2: CHF U4H System Architecture ........................................................................ 11  
Figure 3: COPD U4H System Architecture ...................................................................... 12  
Figure 4: COPD Intervention timeline for U4H ................................................................. 13  
Figure 5: HTN U4H System Architecture ........................................................................ 13  
Figure 6: Generic Remote Monitoring System Diagram (Continua) .............................. 18  
Figure 7: Finnish Telehealth Technical Architecture Diagram ....................................... 19  
Figure 8: Nord Pas de Calais Hypertension Remote Monitoring Architecture ................ 21  
Figure 9: German Telehealth Technical Architecture Diagram with Mobile Phone Used as Communication Hub ................................................................. 22  
Figure 10: Greek Telehealth Technical Architecture Diagram ....................................... 23  
Figure 11: Depiction of CardGuard Gluco Module used with mobile phone (Greece) ......................................................................................................................... 24  
Figure 12: South Norwegian COPD Telehealth Technical Architecture Diagram ....... 26  
Figure 13: Norwegian Service Oriented Architecture (SOA) Diagram ......................... 27  
Figure 14: Norwegian home telehealth devices ................................................................ 27  
Figure 15: Norwegian End-To-End COPD Telehealth Monitoring Architecture ........... 28  
Figure 16: Slovenian System Architecture for diabetes and congestive heart failure using Health Insight Solutions product ......................................................... 31  
Figure 17: Basque Country CHF Service Architecture ..................................................... 32  
Figure 18: Basque Country CHF Architecture Version II ................................................ 32
Figure 19: Basque Country Home Medical Devices .............................................................. 33
Figure 20: Basque Country Service Oriented Architecture (SOA) Bus Structure........ 34
Figure 21: Scottish System Architecture for CHF and COPD.......................................... 35
Figure 22: Scottish Network Architecture for CHF ............................................................ 36
Figure 23: Scottish System Architecture for Diabetes ..................................................... 38
Figure 24: Wales DM and COPD Telehealth Service Architecture ................................. 39
1. Introduction

1.1 Purpose of this document

The Industry Advisory Team (IAT) was asked to analyse the technological platforms used in the current project, to provide advice for the evolution of current services and their integration and converge towards standard platforms, and monitor progress. Twice in the course of the project the IAT is to deliver a report with technical recommendations. This present document is the first: D5.2 – “Technical documentation and Recommendations”.

The report describes the initial architecture baseline of each of the pilot sites regarding their technical architecture, and devices, infrastructure and standards used. It also documents the state of the industry at the time of the document publication.

Before publication, this document was reviewed by the members of the United4Health Industry Advisory Team (IAT).

1.2 Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADSL</td>
<td>Asymmetric Digital Subscriber Line</td>
</tr>
<tr>
<td>AHD</td>
<td>Application Hosting Device</td>
</tr>
<tr>
<td>BT</td>
<td>Bluetooth</td>
</tr>
<tr>
<td>CDA2</td>
<td>Clinical Document Architecture version 2</td>
</tr>
<tr>
<td>COPD</td>
<td>Chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td>CTI</td>
<td>Computer telephony integration</td>
</tr>
<tr>
<td>CUI</td>
<td>Clinical User Interface</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular Diseases</td>
</tr>
<tr>
<td>DHDN</td>
<td>Danish Health Data Network</td>
</tr>
<tr>
<td>DM</td>
<td>Diabetes Mellitus</td>
</tr>
<tr>
<td>DMZ</td>
<td>De-Militarised Zone</td>
</tr>
<tr>
<td>EAI</td>
<td>Enterprise Application Integration</td>
</tr>
<tr>
<td>EDI</td>
<td>Electronic Data Interchange</td>
</tr>
<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
</tr>
<tr>
<td>ECG</td>
<td>Electrocardiography</td>
</tr>
<tr>
<td>ESB</td>
<td>Enterprise Service Bus</td>
</tr>
<tr>
<td>Glucometer</td>
<td>A medical device for determining the concentration of glucose in the blood</td>
</tr>
<tr>
<td>GPRS</td>
<td>General Packet Radio Service</td>
</tr>
<tr>
<td>HBGM</td>
<td>Home Based Glucose Monitoring</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>HDP</td>
<td>Health Devices Profile</td>
</tr>
<tr>
<td>HIS</td>
<td>Health Information System</td>
</tr>
<tr>
<td>HRN</td>
<td>Health Reporting Network</td>
</tr>
<tr>
<td>IAT</td>
<td>Industry Advisory Board</td>
</tr>
<tr>
<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
</tr>
<tr>
<td>ITI</td>
<td>Information Technology Infrastructure (in IHE model) domain</td>
</tr>
<tr>
<td>MDMW</td>
<td>My Diabetes My Way (Scotland)</td>
</tr>
<tr>
<td>LAN</td>
<td>Local Area Network</td>
</tr>
<tr>
<td>PAN</td>
<td>Personal Area Network</td>
</tr>
<tr>
<td>PCC</td>
<td>Patient Care Coordination (In IHE model) domain</td>
</tr>
<tr>
<td>PCD</td>
<td>Patient Care Device (in IHE model) domain</td>
</tr>
<tr>
<td>Pedometer</td>
<td>A device that counts each step a person takes and can calculate the distance travelled</td>
</tr>
<tr>
<td>PHR</td>
<td>Personal Health Record</td>
</tr>
<tr>
<td>PTSN</td>
<td>Public Telephone Switched Network</td>
</tr>
<tr>
<td>PUI</td>
<td>Patient User Interface</td>
</tr>
<tr>
<td>Pulse oximeter</td>
<td>A medical device that indirectly monitors the pulse rate and oxygen saturation of a patient's blood</td>
</tr>
<tr>
<td>SOA</td>
<td>Service Oriented Architecture</td>
</tr>
<tr>
<td>Spirometer</td>
<td>A device for measuring the volume of air exhaled by the lungs</td>
</tr>
<tr>
<td>UMTS</td>
<td>Universal Mobile Telephone Service</td>
</tr>
<tr>
<td>VPN</td>
<td>Virtual Private Network</td>
</tr>
<tr>
<td>WAN</td>
<td>Wide Area Network</td>
</tr>
<tr>
<td>XDS.b</td>
<td>Cross-Enterprise Document Sharing-b IHE profile</td>
</tr>
<tr>
<td>XDW</td>
<td>Cross Enterprise Workflow IHE profile</td>
</tr>
<tr>
<td>XTHM-WD</td>
<td>Cross Enterprise TeleHome Monitoring Workflow IHE profile</td>
</tr>
</tbody>
</table>
2. Background

2.1 United4Health

2.1.1 Overview and Participants

United4Health is a European project, co-funded by the European Commission, that is implementing large-scale real-life telemedicine services implementations for the validation and subsequent evaluation of normalising the implementation and delivery approach of telehealth services within exiting clinical workflows. It is using a combination of pilot sites that are providing their insight from the previous Renewing Health Project and attempting to bring telehealth solutions and deployment to scale and normalisation within the delivery of healthcare services in general. It involves fourteen regions in ten countries for the telemonitoring and treatment of chronic patients suffering from diabetes mellitus (DM), chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF) or hypertension (HTN). The fourteen participating regions are:

- Czech Republic: Northwest Moravia
- Finland: South Karelia (Etelä-Karjala)
- France: Nord Pas de Calais
- Germany: Land Berlin
- Greece: Central Greece (Στερεά Ελλάδα)
- Italy: Campania, Sicilia
- Norway: Northern Norway, Southern Norway
- Slovenia: Slovenia
- Spain: Basque Country, Galicia
- UK: Scotland, Wales

More information about the consortium partners in each region can be found on the project website at www.united4health.eu. Additional partners of the consortium that serve in an advisory function include: The European Patients Forum (EPF), the European Health Telematics Association (EHTEL), the GSM Association (GSMA), the European Coordination Committee of the Radiological, Electromedical and Medical IT Industries (COCIR) and the Continua Health Alliance (CHA). The latter is in charge of managing the Industry Advisory Team.

2.1.2 Clinical Protocols

2.1.2.1 Diabetes Mellitus (DM)

Figure 1 below depicts the system architecture that all of the pilots sites participating in the diabetes pilot will implement.
The goal and clinical protocol are described below:

- The intervention aims to promote self-care and self-management by encouraging the use of self-monitoring of glucose and lifestyle risk factors, and by providing ongoing health coaching.

- The patient at home uses the provided device for the measurement of blood glucose level. The device, used by the patient, collects the data and sends them to the gateway automatically.

- The gateway device transmits data collected by the patient to the server of a Regional eHealth Centre where it is processed according to local policy, i.e. the data can be made available or forwarded to the appropriate person.

- The telemonitoring software will allow healthcare professionals to monitor and manage the data as locally agreed, including the provision of a summary and access to the web based portal to monitor the patients’ health conditions at any time.

### 2.1.2.2 Congestive Heart Failure (CHF)

Figure 2 below depicts the system architecture that all of the pilots sites involved in the CHF pilot will implement.
The goal and clinical protocol are as described below:

- The patient at home uses the provided devices for the measurement of heart rate, blood pressure, pulse-oximetry and weight (in accordance with the treating physician’s prescription, but at least once per week). Reminders will be sent if the centre does not receive measurements for longer than a week, including a specific question: “Do you feel worse than last week?”

- The telemonitoring devices, used by the patient, collect the data and send them to the gateway wirelessly. The gateway device transmits data collected by the patient to the system server.

- An operator checks the data sent by the patient, accessing them through the portal.

- In case of clinical parameters out of normal range, as set by the treating physician for each patient, the system’s software detects the alert situation and the operator manages it, following the standard protocol set by the physician. He/she contacts the patient to verify the alert. If the alert is verified, depending on its severity, the operator contacts the reference clinician for that patient or follows the alert procedure.

- After notification from the operator, the clinician accesses the relevant portal to check patient data and take the proper actions.

- Any time they need, and not only in the case of an alert, clinicians can monitor the patients’ health conditions via the portal.

### 2.1.2.3 Chronic Obstructive Pulmonary Disease (COPD)

Figure 3 below depicts the system architecture that all of the pilots sites involved in the COPD chronic condition will implement.
The goal and clinical protocol are as described below:

- A patient admitted with a COPD exacerbation is discharged from hospital and provided with a telemonitoring package including video conferencing, together with a pulse oxymeter.

- **Step Down Intervention in three stages:**
  1. **High Level Telemonitoring:** daily tele-consultation (preferably via video-consultation, or telephone if not possible), pulse oximetry and daily symptom questions are uploaded prior to the tele-consultation, and will provide a partially standardised structure to the interview. This level of telemonitoring will be aimed for 10 working days after discharge, but can be a minimum of five days, up to a maximum of 30 days to allow some pragmatism, and better reflect a potential real-life clinical service.
  2. **Moderate Level Telemonitoring:** daily pulse oximetry and symptom questions uploaded for up to 12 weeks (minimum of four weeks) after discharge.
  3. **Low Level Telemonitoring:** optional symptom management questions and text message behaviour prompts or website links sent to a mobile phone for up to 12 months after discharge.

- Data recorded during High and Moderate Telemonitoring includes: pulse, oxygen saturation and answers to six pre-selected questions on symptoms.

- The respiratory nurse specialist will contact the patient for video / telephone review or a home visit, or advise to attend hospital according to their discretion. Criteria for hospital treatment will follow local protocols.

Figure 4 depicts the intervention timeline model.
2.1.2.4 Hypertension (HTN)

Figure 5 below depicts the system architecture implemented by the pilot site (France) involved in the HTN chronic condition.

The goal and clinical protocol are as described below:

- Each time the participant executes a measurement with these devices (sphygmomanometer, weight scale, etc.), the results are automatically sent to the information system which stores and analyses them.
• A web portal is available to the participants and medical staff to access the collected results and some additional information:
  - General information about the programme (available to everyone).
  - An e-learning module available to all the persons who have participated to the screening programme (but not necessarily entered the healthcare programme).
  - A complete view of the participant’s file, available only to the participant in the healthcare programme and authorised medical staff (each profile can only view the necessary information).

• Email and SMS notifications can be sent to the participant and to the authorised medical staff (if agreed to at registration).

2.2 The Industry Advisory Team

Although integration of the service solutions at regional level is the highest priority for the Project partners, the use of international standards and the progressive convergence towards common interoperable architectures was equally sought to prepare and facilitate their subsequent scaling up to national and European levels. To facilitate the input and advice from industry, Continua Health Alliance was asked to join the consortium.

Continua Health Alliance is a non-profit, open industry coalition of healthcare and technology companies joining together in collaboration to improve the quality of personal healthcare. Continua is dedicated to establishing a system of interoperable personal health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals and provides the opportunity for truly personalised health and wellness management. Continua has more than 200 member companies including multinational companies and SMEs. Continua was founded in 2006 in the United States; its European office was incorporated in Belgium in 2008. (More information can be found at www.continuaalliance.org.)

Continua was asked to operate an Industry Advisory Team (IAT) of experts with competence in management of clinical data, standards, open sources, business trends in the Personal Health System sector, etc., and to manage the communication and the knowledge transfer between the Industry Advisory Team and the project team and pilots. Specifically the IAT is tasked:

“[… ] to provide advice to the Consortium from companies and people with profound knowledge of the technologies available and of the market trends. The [IAT] will bring together experts with competence in management of clinical data, standards, open sources, business trends in the Personal Health System sector, mobile communications, semantic integration etc.”

“The main objectives of this WP5 are as follows:

• Bring together a team of experts in several fields from industry leaders in the eHealth sector.

• Manage the communication and the knowledge transfer between the members of Industry Advisory Team and the Project Team in an efficient and effective manner to secure the success of the pilots and the further scaling up of the services.
• Analyse and advise pilot regions on standards for interoperability between platforms and devices.
• Analyse the regulatory environment to identify barriers to deployment of telemedicine and interoperable, multi-vendor device chains.
• Provide education both inside and outside the Project on standards, interoperability and regulatory issues affecting deployment.

COCIR, founded in 1959 and headquartered in Brussels, counts today more than 25 member companies and thirteen national member associations in the radiological, electromedical and healthcare IT industry in Europe. It supports its members on issues which affect the medical technology sector and works with various organisations promoting harmonised international standards and fair regulatory control that respects the quality and effectiveness of medical devices and healthcare IT systems. (See www.cocir.org.)

The GSM Association (GSMA) represents the interests of the mobile telephone industry, with a membership of nearly 800 of the world’s mobile operators from more than 200 countries, as well as 200 other companies in the broader mobile ecosystem, including handset makers, software companies, equipment providers, and others. GSMA’s end goal is to drive the growth of the mobile communications industry. GSMA has offices in the Americas, Europe and Asia, with its headquarter in London, UK.

Continua Health Alliance’s European Policy Working Group has been supervising the management and deliverables of the Industry Advisory Team. Principal writer and researcher of the reports has been Bridget Moorman, Continua Health Alliance’s Technical Manager. The IAT has been serviced by Michael Strübin, Continua Programme Manager Europe. Principal contacts at COCIR and GSMA have been Léa Coulet (COCIR) and Anna Campbell (GSMA).
3. The United4Health Project

3.1 Overview and generic technical architecture

The fourteen United4Health telemedicine trials involve the remote monitoring and treatment of chronic patients suffering from diabetes, COPD or cardiovascular conditions. The services are designed to give patients a central role in the management of their own diseases, fine-tuning the choice and dosage of medications, promoting compliance to treatment, and helping healthcare professionals to detect early signs of worsening in the monitored chronic conditions.

There are three main differences between the U4H project and the preceding project, Renewing Health.

- The nature of the trial is observational.
- The telemedicine service must be integrated into the regular continuum of care, i.e. be offered to any patients who meet the entry criteria, and the clinical protocol.
- Measured items must be the same across all of the pilot sites.

The purpose of U4H is to ‘normalise’ the provision of telemedicine services into the healthcare delivery process.

All pilot projects in the U4H programme treat at least one, sometimes two of three chronic conditions: Diabetes, Chronic Obstructive Pulmonary Disease (COPD), Congestive Heart Failure (CHF) and Hypertension (HTN). Table 1 shows the breakdown of the regions participating, the diseases they are providing telemedicine services for, and the number of patients they are treating in the U4H project.
<table>
<thead>
<tr>
<th>Chronic condition</th>
<th>New pilots funded by ICT PSP</th>
<th>New pilots funded from other sources</th>
<th>Existing RENEWING HEALTH partners</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Scotland (UK)</td>
<td>Basque Country (ES)</td>
<td>Wales (UK)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5.600</td>
<td>0</td>
<td>400</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>400</td>
<td>200</td>
<td>250</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>5.600</td>
<td>0</td>
<td>400</td>
<td>7.410</td>
</tr>
<tr>
<td></td>
<td>Basque Country (ES)</td>
<td>Wales (UK)</td>
<td>Southern Norway (NO)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>838</td>
<td>0</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>500</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>COPD</td>
<td>838</td>
<td>0</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.038</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wales (UK)</td>
<td>Southern Norway (NO)</td>
<td>Northern Moravia (CZ)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1.250</td>
<td>300</td>
<td>0</td>
<td>80</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>CHF</td>
<td>1.250</td>
<td>300</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>80</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>669</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.830</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTN</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>669</td>
</tr>
<tr>
<td></td>
<td></td>
<td>669</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>669</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7.688</td>
<td>300</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>200</td>
<td>120</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>250</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>669</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>500</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>150</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>70</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>400</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>11.947</td>
<td></td>
</tr>
</tbody>
</table>
While there is considerable diversity of approaches and methods, the pilots’ technical architectures share certain key characteristics. In all projects, the patient and/or home healthcare clinician uses a medical device to measure a physiological parameter or lifestyle information. The device transmits this data by wire or wirelessly (in some cases data input is done manually) to either a mobile phone, computer tablet or a computer application. This pertinent physiological information is forwarded to a healthcare professional either through an outside vendors’ web application, and/or through that pilot country’s electronic health record (EHR) system or electronic medical record (EMR) application. In some cases, a personal health record (PHR) application is used. Some pilots have a feedback mechanism that reminds patients to take their measurements and/or to take follow-up action. The specifics of what is being collected for each chronic condition are discussed in the following country descriptions and presented in section 4.1.

From a technical perspective, the pilots in general share the functional set-up as shown below.

**Continua E2E Architecture**

![Figure 6: Generic Remote Monitoring System Diagram (Continua)](image)

The above illustration is a generic rendering of a remote monitoring system. It consists of the patient’s medical device with Personal Area Network (PAN), Local Area Network (LAN) or Touch Area Network (TAN) capability. The medical device connects with an Application Hosting Device (AHD), for example a mobile device, personal computer or communications hub, which, in turn, connects to a Wide Area Network (WAN) device. The WAN device interfaces to the Health Reporting Network (HRN) device. For current Continua certified systems in the field, these connections facilitate one-way communication. However, Continua is in the process of approving new bi-directional interfaces in the next guidelines release.
To summarise, the data transmitted in United4Health pilots consists of physiological measurements from a device and/or self-reported information from patient (could be a physiological measurement). This data is then sent to an intermediate server with clinician access, sent to a PHR application (outsourced or internal to clinician provider), and/or sent to EHR/EMR (outsourced or internal to clinician provider). Additionally, in some pilots, information is sent to the patient from a clinical source for educational purposes and/or reminders.

The following sections contain descriptions of the various country pilots in the United4Health project along with their actual technical architectures.

3.2 Czech Republic, Northwest Moravia

The Czech Republic is participating in U4H with the chronic conditions of Diabetes and Congestive Heart Failure. At the time of writing, they are still in procurement, but hope to secure Continua compliant devices and system. Moreover, they hope to use a ‘cloud’ service where the server is located at the supplier “safe” site with an internet connection. Additionally, the medical devices and patient’s gateway are interconnected via Bluetooth; the data are then transmitted over mobile radio network (GSM, UMTS) to the internet and server. They will not connect this system to their Hospital Information System in the beginning, but hope to integrate the services at a later date.

3.3 Finland, South Karelia

Finland is participating in U4H with the chronic condition of Diabetes. The Technical Architecture Diagram for the Finland pilot is shown below.

![Figure 7: Finnish Telehealth Technical Architecture Diagram](image)

In Finland’s procurement documents, a preference was specified for the use of the Continua 1.0 guidelines at Interface 1 in the diagram above. Due to the limited availability of Continua-compliant measurement devices, proprietary interfaces were still used in the pilot. However, the use of open database schemas for the PHR database has been specified in order to allow connectivity with other systems (Interface 6). Future integration by enterprise application integration / enterprise service bus (EAI/ESB) will be taken into account in the design of the self-
management server. This ensures it will be compatible with the service oriented architecture (SOA) and web based platform which provides a wide range of generic services, such as authentication, for various information systems in the Eksote area. (Eksote is the acronym for the South Karelia Social and Health Care District.) In the pilot phase, the telemedicine equipment was not integrated with other IT systems, but integration interfaces are required for further development.

3.3.1 Blood glucose meter

Blood glucose meters or glucometers are CE-approved. In the pilot, patients used two types of glucometers:

1) Basic glucometers. The glucometers are not required to be wirelessly interoperable with the mobile phone. The glucometer measurement data was entered manually into the mobile phone or web PHR application.

2) Interoperable glucometers. It is possible to connect these glucometers to a mobile phone via Bluetooth. When connected, the glucometer should automatically send the measurement result to the self-management server via the inter-connected phone. A data store-and-forward mechanism is also available. In that case, measurement results are stored in the internal memory of the device and the results may then be uploaded later.

Many of the patients had existing glucometers. In these cases, the existing meter was used, which was usually not interoperable with the mobile phone.

3.3.2 Mobile phone

The mobile phones used are standard GSM phones or feature phones (not smart phones). The phones supported wireless connectivity with blood pressure meters and glucometers as defined above.

3.3.3 Web PHR application

For U4H, the web PHR application will be integrated with the portal (ww.hyvis.fi) to provide functionality to view and manage personal health data stored in the PHR database, and to support the self-management process. The application provides user interfaces for patients, care personnel and administrators. All interfaces are browser-based. The core functionalities are:

- Storage and management of personal health data entered by the patient, providing the possibility to view data entered by patients and care personnel.
- Support for safe messaging (off-line) between patient and care personnel based on a secure https connection between the browser and the self-management server.
- Creating and maintaining personal self-management plans.
- Rule-based provision of alerts, reminders and feedback for patients and caregivers.
- Protection of information against unauthorised use.
- Applications receive data via web services or other standard integration protocols.
The service allows users to manually enter home blood glucose results. In the future, automatic uploading of blood glucose results from telemonitoring device will be available. The patients will use their current home glucose monitoring device.

3.4 France, Nord Pas de Calais

Nord Pas de Calais was the only participant with the HTN chronic condition. Below is a diagram of their system architecture supporting U4H.

---

**Figure 8: Nord Pas de Calais Hypertension Remote Monitoring Architecture**

Nord Pas de Calais, France, contracted with Malakoff Médéric to technically integrate the HTN program which is officially called Vigisanté. Malakoff Médéric designed a system which used Parsys’ Telemedicine Box to measure blood pressure, weight, 12 lead ECG and medication adherence in the patient's home. The Parsys Telemedicine Box communicates with the medical devices via Bluetooth, and then communicates with the data centre via GPRS. The ECG data was validated via a clinician web connection using a product from Inovelan which provides cardiology information management (verification and validation of ECG readings) via web access to health data. The Inovelan product also provided a web application front-end for patients, GPs and nurses to all of the patient data in this study. Orange Business solutions provided all of the telecommunication connections, the data storage solution (which was branded by the national health service) and the secure web access.

3.5 Germany, Berlin

Germany is participating with the chronic conditions of Diabetes and COPD. The German pilot in Berlin has a mature remote telemonitoring architecture developed in partnership with Pflegewerk, an assisted living complex in which residents are remotely monitored both physiologically and functionally. The functional monitoring is done through 'smart-home' technology. The technical architecture diagrams
below depict the different monitoring devices and communication hubs used for remote telehealth monitoring. The monitoring devices are connected to a mobile device, namely a smart phone, which collects the data and sends them to a centralised database. These data are compared with multi-valued threshold levels; statistics are collected and stored in an electronic Patient Health Record. There a doctor, a family member, the patient or any other person explicitly authorised for this by the patient himself can look at the situation, and notice any values that may give rise to doubt in a timely fashion and act accordingly.

Measurements are taken directly by the patient himself, where possible. Where appropriate, however, the assistance / coaching of a nurse is provided. If necessary, alarms are sent to family members, caregivers and/or doctors. Otherwise, the assisting nurse can immediately provide the necessary care. A telephone contact with the patient is made more frequently than before.

![HIS ANDROID COMMUNICATION ARCHITECTURE](image)

**Figure 9: German Telehealth Technical Architecture Diagram with Mobile Phone Used as Communication Hub**

The technology of the telemedicine application in German mainly uses three sorts of devices:

- Measuring devices equipped with Bluetooth interface to send data to a suitable receiving device. Such equipment has been on the market for a time, but is not yet widely used. The Bluetooth interface increases the cost of the equipment and makes it mainly suitable for telemedicine applications. As these applications increase in number in the near future, the devices will become more affordable.

- Smart phones as a receiver of the measurement data. These are becoming more and more available and therefore also affordable, and quality is
improving very rapidly. This is important to insure that the measurements are right and get to the right place at the right time.

- A web-based database to store the data and an application to manipulate them, and to make some calculations and presentation (e.g. in the form of charts). This is also a technology that is not new, but it is being improved dramatically; one of the challenges of the application is keeping up with these technological improvements.

At the moment, the application used in Germany is a fairly stand-alone and proprietary application, but steps are being taken to ensure this does not remain so. Integration with the electronic patient records of Pflegewerk is under discussion with the providers of the two software solutions. Other software solutions are being investigated, that will allow integration of the application both with the patient management software of Pflegewerk, and with a future German centralised patient health records.

3.6 Greece, Central Greece

Greece built upon a previous pilot and infrastructure and updated the infrastructure and system for the U4H pilot. They are participating with the chronic condition of Diabetes. The Technical Architecture Diagram of the Greek pilot is shown below.

![Figure 10: Greek Telehealth Technical Architecture Diagram](image)

Greece uses the CardGuard system which provides a web-based PHR called PMP4 for both patient and clinician access. The medical devices used are designed to interface to the PMP4 system. Therefore from an interoperability standpoint, this is a closed system provided by one vendor.

Pictures of the glucometer interfacing to the mobile phone are shown below.
3.7 Italy, Calabria

Calabria, Italy is participating with the chronic condition of Diabetes. They have procured devices and a central Diabetes Management server system from Johnson & Johnson (Lifescan and Eurotouch 10). The patient uses the device provided at home to collect HBGM measurements according to the scheme indicated by the Consultant Diabetologist and using the software provided by the device. The patient or their caregiver then transfers the glucose data to the online computer weekly through a cable with a USB port, and then transmits the data collected to the server at a service centre through the gateway. A 'cloud' server which has the Eurotouch 10 Diabetes Management software interfacing with the Lifescan glucometers will be networked to the computers of the Diabetes Centres participating in the study. The blood glucose data of all the patients enrolled in the project will feed into a single Eurotouch 10 database, and be tracked for each individual patient, constantly and regularly, by the registered nurse responsible for the surveillance and integration between the sites.

Eurotouch Home is software dedicated to people with diabetes, for the collection and processing of self-monitoring blood glucose data with sections (modules) that manage different areas of the clinical history of the user. Data management functions transform the data into a graphical representation of self-monitoring that allows the interpretation of blood glucose data in the light of variables such as meals, nutrition, insulin therapy, and physical activity. There is a therapy section devoted to the recording of drug therapy. Exams are given in the section titled “blood tests and other clinical parameters”, and a complications section is devoted to the recording of the user's other clinical information.
3.8 Italy, Campania

Campania, Italy is participating with the chronic condition of Diabetes.

3.9 Norway, Northern and Southern

Norway is participating with the chronic condition of COPD. To support U4H, a medical team will be established consisting of dedicated COPD nurses at the telemedical central, GPs (local doctors), and COPD specialists at Sørlandet Hospital. The technical solutions to be implemented will give access to the patient’s daily measurements and reported questionnaires for all the healthcare partners, within a secured solution implemented in the Norwegian Health Network.

3.9.1 Legal and Security Requirements in Norway

The legal requirements for access to electronic health records in Norway are limited to be only the employees within the actual organisation responsible for the patient's treatment. There are currently no methods for shared access across organisational borders. However, within the Norwegian healthcare services, all actors can send electronic messages based on a defined ebXML as the syntax for a national message standard. According to existing routines, a discharge message will be sent from the hospital to both the patient's GP and the municipality healthcare services.

In the Norwegian U4H project, the legal aspects for shared access to electronic health records have been thoroughly investigated. In a report of legal and security aspects, it has been clarified that based on the patient's consent, the information needed in the project can be shared if the storage and access control mechanisms meet Norwegian requirements. In the patient consent form, the patient will be asked to give his/her permission to share medical information between the healthcare personnel involved.

In the project, a dedicated server and database will be established as a tailored “Treatment Pathway Health Record” for temporary storage of patient information. In the clinical protocol step of “After terminating the low level of TMon”, the stored medical data for the patient will be exported to the traditional electronic health record (EHR) for permanent storage; anonymised data will be exported to the project report database.

For secure access to medical information, the servers used in the U4H project will be implemented within the secure framework of the Norwegian Health Network. Sykehuspartner, which is a public company responsible for the ICT infrastructures for hospitals in South Norway, will set up the required servers. A dedicated secured VPN tunnel will be defined for communication from a tablet-PC near the patient for upload of daily vital signs measurements and questionnaire information. This VPN setup is defined according to the requirements and specification made available from the Norwegian Health Network. In addition, there will be secure video communication solutions implemented based upon existing infrastructure established within the Norwegian Health Network. This video communication solution will use the Cisco product Jammer Video Communication; the corresponding address book is defined within the Norwegian Health Network supporting all video conference systems.
3.9.2 Technical Telehealth Set-up

In the South Norway setup, a Vital Sign server will be installed with secure access controlled by AAA-server (Authentication, Authorisation and Accounting). From the patient’s tablet-PC, a dedicated VPN tunnel will be established in order to have a secure upload of data to the server. The tablet-PC will be equipped with a SIM-card and use mobile data communication based on 3G/4G solutions.

Healthcare personnel will need to be within a secure zone in the Norwegian Health Network, and they will need a digital-ID on a smartcard for secure log-on to the server. Those principles are illustrated in the Figure 12 below.

In the North Norway trial, the system setup will be identical; however, it will be personnel at University Hospital of North Norway who will take care of the daily patient follow-up.

The technical architecture diagram for the South-Norway pilot is shown below.

![South Norwegian COPD Telehealth Technical Architecture Diagram](image)

Figure 12: South Norwegian COPD Telehealth Technical Architecture Diagram

3.9.3 Treatment Pathway Health Record (TPHR) and Information Integration Portal (IIP)

For the integration of medical devices and questionnaire information, University of Agder has developed a dedicated Information Integration Portal (IIP) implemented in the project setup. This portal is based upon open standards for publishing sensor information (restful web services), and a personal Electronic Health Record database will subscribe to this portal in order to import all data uploaded from the patient’s home. The Treatment Pathway Health Record (TPHR), developed by University of Agder and Devoteam Solutions, will act as a collaborative dashboard in order for the involved healthcare personnel to share both the patient’s recordings and documentation of actions taken. This solution is based upon secure access both by healthcare personnel and for the patient to upload new data to the centralised server database.
3.9.4 Tablet-PC, devices and software

In the Norwegian trial, the tablet-PC will be based on Windows 8 for security reasons. Dedicated software developed by University of Agder is implemented in the tablet-PC. The pulse oximetry device will be a Nonin PureSat, with the spirometry being a Vitalograph 4000 asma-1. Both devices will use a serial Bluetooth communication to the tablet-PC. On the tablet-PC, there will be a SQL database for storage of vital signs measurements and results from the daily questionnaires. The hard disk on the tablet will be encrypted, and secured by a PIN-code for the user’s log-on. No other Windows operating system functions will be available to the user to meet the high security requirements. All software used in the Norwegian systems will be declared as medical software.

Dedicated medical devices and a Windows 8 Tablet-PC with medical software

The end-to-end (E2E) connectivity is based on a secured VPN tunnel from the patient’s tablet-PC, and standard mobile data communication (3G/4G) to a dedicated VPN Firewall at the Norwegian Health Network. Before implementation of
the system, a security and risk analysis will be carried out in order to guarantee security actions required by specifications and legal requirements in Norway.

Figure 15: Norwegian End-To-End COPD Telehealth Monitoring Architecture

3.10 Slovenia

Slovenia is participating in the remote monitoring of the chronic conditions of DM and CHF. They will outsource the service for the home and telehealth centre to Health Insight Solutions (HIS). This solution is the similar to that used by Germany detailed in section 3.5. They are planning to use the wireless set-up, with the clinicians using an Internet portal to access the patient data. The server which hosts the HIS portal will initially be part of the SB-SG hospital, behind healthcare enterprise firewalls. It is hoped that later the portal will be fully integrated in the national healthnet infrastructure (zNET). HIS uses the following medical devices for physiological monitoring: IEM Librograph weight scale, Card Guard ECG, Nonin Onyx II pulse oximeter, Cignus Profiline glucometer, TaiDoc TD ear thermometer, and the Vitalograph asma-1 spirometer. Slovenia will use BlueTooth 3.0 or higher versions of these devices. For the home gateway, HIS uses an application for any Android version 2.3 or higher device (tablet or mobile phone).

The workflow for supporting diabetes is as follows:

- Diabetic patients - potential users will be invited to participate in research within the U4H project.
- When the patient accepts the invitation, he/she will sign a written consent letter, and will receive adequate training covering the telemonitoring service and use of the devices which are a part of it.
- If after the training the patient is still willing to participate, a glucometer with stripes and a smartphone with a running app will be given to the patient at the training session. The patient will be asked to test the equipment and the service.

The telemedicine service for diabetic patients will work as follows:

- All patients will be monitored for 12 months. Once a week they will provide six measurements taken during the same day: before and after breakfast, before
and after lunch and before and after dinner. In exceptional cases, these measurements will be provided daily.

- If all measurements are within the expected range, no actions will be taken.
- If any measurements are out of expected range, patients will provide an additional six measurements the next day.
- If any measurement is out of the expected range, or data trend goes out of range, a planned response will be taken by the system and the medical staff.
- Weekly reports will be generated by the system that will be sent by email to the diabetologist’s email box. The diabetologist’s team will regularly review them, add comments, and sign them. If needed, they will react in accordance with their traditional protocols.
- Monthly reports will also be generated by the system, and will be sent by email to the diabetologist’s email box.
- The signed monthly reports will be sent regularly to diabetic patients by ordinary mail.
- Regular six month visits to a diabetologist will be maintained during the duration of the telemedicine monitoring. At the visits, the diabetologist and the patients will review and discuss the telemetrically gathered data.
- The telemetrically supported patients will receive technical support when sought (help desk, on-site technical support, glucometer and mobile phone maintenance service).
- The patient will have an optional communication channel to contact the regional centre operator by phone. This means of contacting medical staff is a part of the already established system. The same channel will be used by the regional centre operator when the patient is contacted.
- In case of emergency, the patient has the possibility to activate the established emergency healthcare network.

The workflow for supporting CHF is as follows:

- CHF patients - potential users will be invited to participate in research within the U4H project.
- If the patient accepts the invitation, he/she will sign a written consent letter and will receive training covering the telemonitoring service and use of the devices which are part of it.
- If after the training the patient is still willing to participate, all three measuring devices and a smartphone with a running app will be given to the patient at the training session. The patient will be asked to test the equipment and the service.

The telemedicine service for CHF patients will work as follows:

- All patients will be monitored for 12 months, and will provide telemetric data at least once a week. They will be encouraged to take measurements and provide data every day at the same time.
- If all measurements are within the expected range, no actions will be taken.
- If any measurement are not within the expected range, or data trend goes out of range, a planned response will be taken by the system and medical staff.
Monthly reports will be generated by the system that will be sent by email to the cardiologist’s email box. The cardiologist’s team will regularly review them, add comments, and sign them. If needed, they will react in accordance to their traditional doctrine.

The signed monthly reports will be sent regularly to the CHF patients by an ordinary mail.

Regular six month visits to the cardiologist’s team will be maintained during the duration of the telemedicine monitoring. At the visits, the cardiologist and the patients will review and discuss the telemetrically gathered data.

The telemetrically supported patients will receive technical support when sought (help desk, on-site technical support, measuring devices and mobile phone maintenance service).

The patient will have an optional communication channel to contact the regional centre operator by a phone. This means of contacting medical staff is a part of the already established system. The same channel will be used by the regional centre operator when the patient is contacted.

In case of emergency, the patient has the possibility to activate the established emergency healthcare network.

Slovenia intends to integrate the U4H system in the following way.

The server, on which the telemedicine service for telemetric support of diabetic and CHF patients will be based, will be fully integrated into the SB-SG hospital information infrastructure. Slovenia plans to use a virtual server within the hospital IT centre infrastructure to run the telemedicine service. This means that it will run in a safe environment where all information safety measures will be guaranteed.

Using this solution, the project team will be able to have in place all measures targeting privacy issues when handling sensitive personal data. The hospital medical and technical staff already have in place high level of information system security measures.

The architecture for the Slovenian implementation is below.
3.11 Spain, Basque Country

The Basque Country is participating in the chronic condition associated with CHF. They are integrating home monitoring via a web service (WS) that allows a home health gateway device to send the biometric information to platforms implementing the communication of this service. Both the configuration of the monitor from the platform, and the data analysis to obtain processed and classified information is possible.

The home telemonitoring platform is integrated with the alarm management platform and Osakidetza's Electronic Health Record (EHR) via WS and Web Application Firewall (WAF). (Osakidetza is the Basque Country’s national health care provider). Thus, the telemonitoring data collected by the gateway device are incorporated in the patient’s EHR through Osakidetza’s WS. The integration complies with Osakidetza's strategic criteria which determine that the clinical information coming from patient's home or HCPs has to be managed through its own systems, reducing the number of interactions between professionals and distinct applications and interfaces. The communication between the Telecare Centre and Osakidetza's information systems is bidirectional.
The selected sensors used for remote monitoring in the home are qualified as Sanitary Products according to the European Directive 93/42/CEE, and have been widely used and validated worldwide proving their high reliability. The selected models are:
- Nonin 9560 Onyx II pulse-oximeter.
- A&D UA-767PBT blood pressure monitor.

The Home Gateway device provided has two options:
- Mymedic II (Tunstall): non-mobile solution.
- CarelineH@me (Saludnova): mobile solution.

![Basque Country Home Medical Devices](image)

**Figure 19: Basque Country Home Medical Devices**

The system integration is based on a Service Oriented Architecture (SOA) and on the implementation of security policies of Osakidetza, which stipulate that all internal WS calls made through the integration bus (OSB) dedicated to Internet area, have to be made by a secure protocol (HTTPS) and applying WSS security policies of signing and authorisation. This architecture requires a certificate of application and implementation of security policies defined by Osakidetza and based, in turn, on Oracle Web Services Manager. This process guarantees the integrity of the messages.

Internet applications can access the services published by internet OSB. In addition, the OSB audits the calls to the web services through Osakidetza’s proprietary policy managed by Oracle Web Service Manager (OWSM). All the services in the OSB are protected by oracle_wss10_x509_token_with_message_sign_service_policy. This policy authenticates the applications through x509 certificate and signs the request and response message. Finally, the Internet OSB delegates the execution to services published on the Intranet where separate instances are deployed irrespective of WS to serve requests from the Internet OSB.
3.12 United Kingdom, Scotland

Scotland is participating in the monitoring of the chronic conditions of CHF, COPD and DM.

3.12.1 Scottish CHF and COPD Architectures

For CHF and COPD, Scotland is procuring the Medvivo Homepod system. The Homepod itself is the central hub, communicating via broadband or 2G/3G/4G to the clinical triaging system, and by Bluetooth / USB to the patient medical devices which are predominantly scales, pulse oximeter, thermometer and BP. Scotland will be using: A&D Bluetooth blood pressure monitors and weight scales; ChoiceMed Bluetooth pulse oximeters; and a Bluetooth thermometer (vendor not identified yet). The system architecture of the Medvivo Homepod system is depicted below.
The Homepod is a tablet based system that integrates to third party medical devices

![Diagram of Scottish System Architecture for CHF and COPD]

**Figure 21: Scottish System Architecture for CHF and COPD**

The Medvivo web and data servers (patient data) are hosted by Piksel (formerly loko).

An additional videoconferencing functional component will be required for the U4H COPD protocol; at the time of writing this is still being investigated for procurement.

For CHF, the Homepod, which consists of tablet hardware with either Windows or Android, is the central hub, communicating via broadband or 2G/3G/4G to the clinical triaging system, and by Bluetooth or USB to the patient medical devices. The medical devices used for the heart failure workstream are A&D Bluetooth blood pressure monitor, and A&D Bluetooth weight scales. The Homepod software which interacts with the patient is called the PUI or patient user interface. It supports the patient protocols and interacts with the medical devices.

The clinical user interface (CUI) is the patient management software that resides on a clinician’s PC or tablet, or on a terminal in the triage / call centre. The CUI is the management console that interacts with the patient and Homepod in allowing the patient record to be set up, protocols to be configured, readings to be monitored and triaging management. There are two versions of the CUI; Windows which has extensive functionality and configurability, and a web version which is lighter and manages all the day-to-day activities of a clinician and triaging centre.

The Homepod is used to collect patient vital signs data from the patients’ home, and then feed that data to a central server, sitting behind the N3 firewall (see Figure below).
Typical connection between the Homepod and the server is securely over GPRS. In areas of poor / no signal, POTS (dial up modems) are used. Connection via home-based ADSL / Internet is readily available, but generally it is policy not to use public networks for security / data compliance reasons.

The service is hosted within the N3 network, using both N3 and secure VPN authentication. The service utilises the existing N3 infrastructure for hosting and security.

All data transfers between the Homepod and central server (behind the N3 firewall) are transported over a secure 256 bit AES encrypted private APN. The APN connection used depends upon the communication method employed (GPRS / ADSL / POTS). The APN exclusively binds the Homepod to the server.

The data upload takes place immediately upon the ending of a patient session. In the event that a connection is not available, the Homepod will persist at pre-set time intervals until it is successful. This is the only point in time that results data are stored (encrypted) on the Homepod. After a successful transmission, the data registers are emptied.

Data downloads to the Homepod fall into two scenarios. Firstly, remote system updates or patient protocol changes, and secondly, a patient's request to retrieve their results. The first scenario can either be initiated automatically by the Homepod once the patient has entered their PIN, or on a polling basis. The second scenario is on a demand basis each time the patient requests some history. The update process is very scalable and sensitive to bandwidth / load balancing constraints.

Figure 22: Scottish Network Architecture for CHF
Data is transported to and from a clustered SQL server database through a set of web services within a DMZ environment. This method of operation is used for both the Homepod and the CUI. It is also used for reporting and interfacing to third party systems. HL7 interfaces are also supported in this way. There are no direct connections to the database.

In relation to third party integration with the Homepod database, the CUI is able to support multiple coding schemas. The coding schemas depend on the type of system requiring integration. Integration with EMIS LV and INPNS VISION, using READ2, is being pursued in Scotland.

### 3.12.2 Scottish Diabetes System Architecture

For Diabetes, Scotland is going to expand their existing Diabetes management services: Scottish Care Information – Diabetes Collaboration (SCI-DC) started in 2002. Additionally, an online educational resource called My Diabetes My Way (MDMW) was implemented in October 2008. An ICT system now links MDMW to SCI-DC data to allow patients access to their clinical information, sourced from all relevant diabetes information sources. This personal health record is available to every individual with diabetes in Scotland aged 16 or older, regardless of their geographical location or demography. The ability to enter home-recorded results was implemented in January 2013. This allows users to manually enter home blood glucose results, blood pressure, cholesterol, weight and smoking status.

For U4H, technology will be implemented that facilitates automatic uploading (versus manual entry of values) of home based glucose monitoring (HBGM) into SCI-DC and the MDMW patient portal. This will allow sharing of detailed blood glucose results and trend analysis during consultations or online discussions. Integration of HBGM will be achieved through pre-existing technology that allows easy upload of data regardless of the device / manufacturer, and gives a standardised display of results. A collaboration with the commercial company Diasend has been chosen as it is already implemented within a number of Health Boards in Scotland, thus making integration easier and more efficient. The patient will use their current home glucose monitoring device.

From a workflow perspective, the clinician initiates the workflow by obtaining the patient’s consent to receive HBGM results from their monitoring device. Once enrolled into Diasend, user credentials are entered into the patient’s record to initiate a one-off record linkage process. This process generates an internal identifier (Diasend ID) which is then matched to the patient master patient index (CHI) in SCI-Diabetes. A batch processing job then collects new results from Diasend, stores them against the patient record in SCI-Diabetes, and transfers it to MDMW. The patient can then either view their results directly in MDMW, or click directly into Diasend to view a copy there. This process allows the patient and all members of the healthcare team access to these results for discussion during physical or virtual consultations.

The HBGM results will be integrated in to the existing SCI-DC clinical information system making the results widely available to patients and clinicians.

Development of the integration of HBGM into MDMW & SCI-DC will be a step by step process and includes:
- **Licensing / Integration**: Adoption and use of Diasend technology for HBGM upload.
- **Remote login to Diasend**: One-off linkage process from Diasend ID to SCI-Diabetes mapped to CHI number; ability to store Diasend login credentials for a patient in MDMW; development of web services to authenticate user; launch window into Diasend; supporting documentation & analysis.
- **Diasend data import**: REST API/ Raw Data Import for Diasend.
- **Record Transfer from Diasend to SCI-DC to MDMW**: Web services to receive data from Diasend; ability to store Diasend patient identification credentials for a patient in SCI-Diabetes; ability to store Diasend patient identification credentials for a patient in MDMW; data linkage processes (Diasend ID matched to CHI, for example); data transfer mechanism; data presentation in MDMW; data presentation in SCI-Diabetes; supporting documentation & analysis.

![Figure 23: Scottish System Architecture for Diabetes](image)

For CHF, the Homepod itself, which consists of tablet hardware with either Windows or Android, is the central hub, communicating via broadband or 2G/3G/4G to the clinical triaging system, and by Bluetooth or USB to the patient medical devices. The medical devices used for the heart failure workstream are A&D Bluetooth blood pressure monitor, and A&D Bluetooth weight scales. The Homepod software which interacts with the patient is the PUI. It supports the patient protocols and interacts with the medical devices.

### 3.13 United Kingdom, Wales

Wales is participating in the monitoring of the chronic conditions of COPD and DM. They are using a telehealth service provided by Simple Telehealth.
COPD patients will enter their data into a Whyzan COPD briefcase containing pulse oximeter, thermometer and computer tablet that uses Bluetooth technology to transmit that data. They will then be given the opportunity to videoconference with their clinician. The medical devices and gateway used are TaiDoc VTrust handheld pulse oximeter, TaiDoc Lever TD ear thermometer, TaiDoc blood pressure monitoring system and Archos computer tablet, respectively.

The devices used for Diabetes participation are glucometers (several brands as patients already have their own glucometers) and smartphones. The glucometer devices are currently not connected directly to a gateway communication hub. Instead, patients will manually enter the information into their smartphone.

All data is transmitted via GPRS to the Simple Telehealth interactive program following a pre-approved standardised or individualised protocol. Disease specific advice and health coaching messages are returned to the patient automatically via Simple Telehealth, or manually by the clinician in case of an alert or a breach of parameters.

Integration of the U4H developed services into the existing Wales ICT infrastructures will be reviewed following the outcomes of the study.

The figure below depicts the Wales architecture.

Figure 24: Wales DM and COPD Telehealth Service Architecture
4. **Summary and analysis**

4.1 **Parameters and data types collected**

Based on the breakdown of pilots along the chronic conditions of Diabetes, COPD, CHF and HTN, the following table gives a summary of the parameters, data types and specific technical capability that will be collected / required in the United4Health Project’s pilots.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Chronic condition</th>
<th>Diabetes Mellitus (DM)</th>
<th>Chronic Obstructive Pulmonary Disease (COPD)</th>
<th>Congestive Heart Failure (CHF)</th>
<th>Hypertension (HTN)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Pressure</td>
<td></td>
<td></td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td>Nord Pas de Calais</td>
<td></td>
</tr>
<tr>
<td>Pulse Oximetry (SPO2), Pulse Rate</td>
<td></td>
<td>Galicia, Northern and Southern Norway, Scotland, Wales</td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td></td>
<td></td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td>Nord Pas de Calais</td>
<td></td>
</tr>
<tr>
<td>Blood Glucose</td>
<td>Berlin, Campania, Central Greece, Galicia, Scotland, Sicilia, Slovenia, South Karelia, Wales</td>
<td></td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Video Teleconference</td>
<td>Galicia, Northern and Southern Norway, Scotland, Wales</td>
<td></td>
<td>Basque Country, Northwest Moravia, Scotland, Slovenia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The following section provides a detailed analysis of devices and transfer protocols before we consider the question of standards compliance.
4.2 Devices, interfaces, and telehealth software capabilities

Below is a summary table of the devices and interfaces used by each pilot, listed separately for each condition where they differ. The monitoring device may be a glucometer, blood pressure cuff, weight scale, spirometer, pulse oximeter, or an ECG.

<table>
<thead>
<tr>
<th>Country</th>
<th>Condition</th>
<th>Monitoring device</th>
<th>Means of Transmission</th>
<th>Aggregation Gateway in Home (Application Hosting Device)</th>
<th>Means of Transmission</th>
<th>Personal Health Record</th>
<th>Electronic Health Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain, Basque Country</td>
<td>CHF</td>
<td>Nonin 9560 Onyx II pulse-oximeter, A&amp;D UA-767PBT blood pressure monitor, patient weight scale</td>
<td>Bluetooth and manual entry (weight)</td>
<td>Mymedic II (Tunstall): non-mobile solution, CarelineH@me (Saludnova): mobile solution</td>
<td>Landline (Internet-Web services), GPRS/3G</td>
<td>Osakidetza</td>
<td>Osakidetza</td>
</tr>
<tr>
<td>Finland, South Karelia</td>
<td>DM</td>
<td>Glucometers- are patient owned so patients use different brands.</td>
<td>Bluetooth 3.0</td>
<td>Nokia 5230 Navi and home computer through web application</td>
<td>GSM, Internet (Web)</td>
<td>Medixine Clinic</td>
<td>Effica (Regional EHR)</td>
</tr>
<tr>
<td>Germany, Berlin,</td>
<td>COPD</td>
<td>SPO2-Nonin 9560 Onyx II Jaeger -Viasys AM1+BT Asthma Monitor (Spirometer)</td>
<td>USB</td>
<td>Arbor Technology Medical Tablet PC M1255/N270 or Mobile phone (HTC Cha-Cha)</td>
<td>Internet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germany, Berlin,</td>
<td>DM</td>
<td>Glucometer – Cignus Diagnostics ProfiLine, IEM Libro-O-Graph mobil</td>
<td>USB, Bluetooth</td>
<td>Arbor Technology Medical Tablet PC M1255/N270 or Mobile phone (HTC Cha-Cha)</td>
<td>Internet</td>
<td></td>
<td>LifeSensor</td>
</tr>
<tr>
<td>Device-Interface</td>
<td>Condition</td>
<td>Monitoring device</td>
<td>Means of Transmission</td>
<td>Aggregation Gateway in Home (Application Hosting Device)</td>
<td>Means of Transmission</td>
<td>Personal Health Record</td>
<td>Electronic Health Record</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------</td>
<td>-------------------</td>
<td>-----------------------</td>
<td>----------------------------------------------------------</td>
<td>-----------------------</td>
<td>-----------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>France, Nord Pas de Calais</td>
<td>HTN</td>
<td>Parsys blood pressure, EKG, weight scale and pill box (medication adherence)</td>
<td>Bluetooth</td>
<td>Parsys Telemedicine Box and Inovelan Web client for EKG management and web access to patient data</td>
<td>GPRS via Orange Business Services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Greece, Central Greece</td>
<td>DM</td>
<td>Glucometer – Card-Guard PMP Self-Check Gluco module</td>
<td>Bluetooth</td>
<td>PDA QTEC 2020i and Vodafone ETEN</td>
<td>GSM (GPRS)</td>
<td>PMP4</td>
<td></td>
</tr>
<tr>
<td>Italy, Calabria</td>
<td>DM</td>
<td>Glucometer – Lifescan, Johnson &amp; Johnson</td>
<td>USB</td>
<td>Home computer and cloud server with Eurotouch 10 (Johnson &amp; Johnson) Diabetic Management Database</td>
<td>Internet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northern and Southern Norway</td>
<td>COPD</td>
<td>Nonin PureSat pulse oximeter, Vitalograph 400 asma-1 spirometer</td>
<td>Bluetooth</td>
<td>Windows 8 Tablet ‘locked’ down; software will be classified as medical software; Cisco Jabber Video teleconferencing software</td>
<td>TeleNorway VPN tunnel</td>
<td>ePHR</td>
<td>Use of Transitional Personal Health Record (TPHR) to meet legal and security concerns; PDF import and export functions to exchange data with existing EHR systems</td>
</tr>
<tr>
<td><strong>Country</strong></td>
<td><strong>Device-Interface</strong></td>
<td><strong>Condition</strong></td>
<td><strong>Monitoring device</strong></td>
<td><strong>Means of Transmission</strong></td>
<td><strong>Aggregation Gateway in Home (Application Hosting Device)</strong></td>
<td><strong>Means of Transmission</strong></td>
<td><strong>Personal Health Record</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------</td>
<td>---------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>Slovenia</td>
<td>COPD, DM</td>
<td>COPD, DM</td>
<td>IEM Librograph weight scale, Card Guard ECG, Nonin Onyx II pulse oximeter, Cignus Profiline glucometer, TaiDoc TD Ear thermometer, Vitalograph asma-1 spirometer</td>
<td>Bluetooth 3.0 or higher</td>
<td>Health Insight Solutions Santigo application on a tablet or other Android 2.3 or higher device</td>
<td>GSM, Internet</td>
<td>Portal access to monitoring information (HIS Santigo portal) via web-based browser. HIS portal will be located at SB-SG hospital initially.  Hope to have HIS Portal available to zNet (Slovenian national health information infrastructure) in future</td>
</tr>
<tr>
<td>United Kingdom, Scotland</td>
<td>CHD, COPD, DM</td>
<td>CHD, COPD, DM</td>
<td>A&amp;D Bluetooth Blood Pressure Monitor, Weight Scale, ChoiceMed Bluetooth pulse oximeter, patient owned glucometers, so many brands</td>
<td>BlueTooth and USB</td>
<td>Medvivo Homepod; DIASEND software combined with SCI-DC and MDMW portals</td>
<td>GPRS, GSM, Internet</td>
<td>MDMW</td>
</tr>
<tr>
<td>United Kingdom, Wales</td>
<td>COPD, DM</td>
<td>COPD, DM</td>
<td>TaiDoc VTrust Handheld Pulse Oximeter, TaiDoc Lever TD Ear Thermometer, TaiDoc Blood Pressure Monitoring System, patient owned glucometers, so many brands</td>
<td>Bluetooth, manual entry</td>
<td>Archos Computer Tablet, mobile phone (video-teleconferencing capability as well)</td>
<td>GPRS</td>
<td>Simple Telehealth Service</td>
</tr>
</tbody>
</table>
Table 4: Pilot Telehealth software capabilities for patients

<table>
<thead>
<tr>
<th>Software Capability Country</th>
<th>Data Visualisation of Vital Signs</th>
<th>Alerting of Deviation/Normal Values</th>
<th>Input of Manual Measurements</th>
<th>Symptoms and Quality of Life Questionnaires Input</th>
<th>Satisfaction Questionnaires Input</th>
<th>Technical Questionnaires Input</th>
<th>Video/Voice or Text Communication with Clinician</th>
<th>Calendar Functions, Appointment Review and/or Petition</th>
<th>Reproduction of Educational Material</th>
<th>Medication Reminders</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain, Basque Country</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Finland, South Karelia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes (text, safety messaging)</td>
<td>Yes, part of eHealth servicing in Eksote</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Germany, Berlin</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>Yes</td>
<td>Yes, on separate portal</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Northern and Southern Norway</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>Yes</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>No, is an option with system, however</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, on separate portal</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>United Kingdom, Wales</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No, but can if wanted</td>
</tr>
</tbody>
</table>
### Table 5: Pilot Telehealth software capabilities for clinical professional

<table>
<thead>
<tr>
<th>Country</th>
<th>Data Visualization</th>
<th>Alerting of Deviation/Normal Values</th>
<th>Prioritisation of Patients According to their Risk Levels</th>
<th>Task Management</th>
<th>Structured Telephone Support (to get data from patients)</th>
<th>Video/Voice or Text Communication with Patients</th>
<th>Video/Voice or Text Communication/Reporting with/to Other Clinicians</th>
<th>Calendar Function: Appointment Review and/or Petition</th>
<th>Careplan Creation, edition and changing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain, Basque Country</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Finland, South Karelia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes, part of eHealth service in Eksote</td>
<td>Yes</td>
<td>No</td>
<td>Yes, text safety messaging</td>
<td>Yes, text safety messaging; data is available to other clinicians</td>
<td>Yes, part of eHealth service in Eksote</td>
<td>Yes</td>
</tr>
<tr>
<td>Germany, Berlin</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No, available on another portal</td>
<td>Yes, comment blog with text; automatic generation of clinician report</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Northern and Southern Norway</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No;</td>
</tr>
<tr>
<td>Slovenia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No, available on another portal</td>
<td>Yes, comment blog with text; automatic generation of clinician report</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>United Kingdom, Wales</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>
Among the key findings are:

- Where data is transmitted electronically, network transmission methods are standards based, while messaging and data formats remain proprietary.
- Mobile phones and smart phones are important data hubs and transmitters.
- There remain important legal and regulatory barriers, e.g. Norwegian laws do not allow a patient-acquired measurement to be directly and automatically transferred into an EHR that is government or healthcare organisation owned.

4.3 Industry

Many pilot projects had difficulties identifying medical devices on the market that could interface with the mobile phones or use the data and network standards as recommended by Continua and IHE-PHD. One participant mentioned that their national market did not seem large enough for many competitors in this realm just yet. Moreover, some of the legal issues regarding use of the native language in all contractual and equipment information was a barrier for new international players to enter their market.

The IAT prepared a country-by-country analysis of telemedicine vendors and products to facilitate the identification of appropriate industry partners (see Appendix B “State of the Industry”). At the beginning of the project, about 60% of the telehealth market was “owned” by the services industry (telecommunications) and 40% was owned by the device manufacturers; there seemed to be no one market leader in any country, which led to intense competition. The market was full of smaller and medium sized players, some of whom may not belong to the standards community of Continua and IHE. As of 2013, that has changed, with Philips, Tunstall, GE Healthcare, BodyTel, Aerotel, Honeywell and Polycom emerging as the dominant (listed in order of dominance) vendors across most of Europe.¹

There are four companies whose products are used in United4Health who are also Continua members: A&D, Health Insight Solutions, Nonin, and Tunstall. These companies might offer a route to implementing Continua certified products in the future. However, interoperability at the device level may only have a minor overall impact. The EN-ISO11073 standards included within the Continua Guidelines provide for interoperability of devices, effectively allowing systems designers some choice of peripherals they recommend. IHE-PCD provides for some integration between a remote monitoring service and an electronic clinical record, but again where health services have been slow to adopt electronic records, this solution is ahead of its time. The market dynamics for remote monitoring would change if the patient-provider interface was opened up – offering patients true choice in the hub device they use, whether mobile phone or a highly usable bespoke device. There are a number of factors that will make this a complex undertaking – including the absence of agreed clinical protocols, and the demands of device regulation.

The market for telemedicine products in Europe is consolidating and maturing. However, the macroeconomic issues within Europe may slow this down considerably intra-regionally, as well as contribute to further fragmentation of the market. The overall market size is a barrier to further investment by suppliers in their products. Interoperability and integration are not yet seen as an engine of

growth. A wider range of offers and the realisation of economies of scale are likely to occur when consumers rather than health systems are able to drive the market. Payment systems and regulation act against this. In particular, regulators have yet to clearly define requirements for interoperable systems, including both traditional medical devices and software. This leaves suppliers managing their risk by retaining proprietary interfaces to maintain control of their system.
5. Conclusions and recommendations

United4Health seeks to promote the use of international standards and the progressive convergence towards common interoperable architectures with a view to subsequent scaling up at national and European levels.

The progression from Renewing Health shows that the telecommunication standards have been followed with regard to network protocols, however, data and messaging standards for healthcare have not been procured. There are still security and legal hurdles for some of the regions, and the idea of ‘normalising’ telehealth / telemedicine into the type of clinical care offered for chronic diseases is at an early stage; the clinical workflow and patient expectation aspects are currently the priority.

There are also other factors at play. It has turned out that users in search of standards-compliant products have had difficulties finding them. Few vendors have brought products to market, and if they have, they may not be compatible with local markets where United4Health projects are required to buy. There may be a number of reasons for this:

- Medical device regulation acts to encourage closed end-to-end monitoring systems by placing responsibility on the suppliers for assuring safety. Players in the mobile industry have expressed concerns, partly driven by regulations in other geographies, about the possibility that a mobile handset used in monitoring could be considered as falling within the scope of medical device regulations.
- Regulation also means that the medical device industry typically works to much longer product lifecycles than is common in IT-related industries.
- Most monitoring systems on the market have been tailored to the complex usability needs of older people. They usually consist of vertically integrated specialised hubs. These hubs do not usually require the use of a smart phone. Moreover, users (especially older people) are not always comfortable with smart phones and their size and interfaces.
- Current interoperability standards have focused on peripheral devices and whole-system integration, and have yet to impact on areas that would truly open up the consumer-provider interface and create fresh solutions.
- Cost could also be a factor, where standards adoption is confined to the premium end of the market and used as a differentiator.

The fragmented nature of the European markets, both nationally and in terms of the purchasing organisations, also means that demand for interoperability has been slow. Some local markets have been intensely competitive, but interoperability has not been seen as a differentiator that would justify the additional investment involved in modifying current systems.

At the beginning of the U4H project, the market for telemedicine products (in Europe and beyond) has progressed with vendor consolidation across Europe. Frost & Sullivan’s 2013 report on the European market for remote patient monitoring summarises it as “gaining momentum, but uncertain times ahead”, mainly due to the economic downturn in several European countries. The benefits of standards and interoperability are slowly proving their value to the more educated buyers, who are asking about or mandating them in their procurements. For others, there is still a learning curve with regard to the benefits of standards based procurement for
remote patient monitoring. As a result, while standards-compliant products are in the pipeline, industry has mixed incentives to bring them to market, dependent upon the region or country procuring the equipment.

Policy makers, consumers, buyers and industry agree on the benefits of interoperability, but the tipping point has not yet been reached European-wide. United4Health represented a unique opportunity, even on a small scale, for common and coordinated action. Promoting standards and interoperability is a task for all stakeholders, and the IAT addresses its recommendations to all.

Achieving better interoperability and scalability of services were beyond the scope and time frame of the United4Health project. However, the project has helped to push in the right direction. The IAT recommended a concerted effort among all players in the project to help. Additionally, several of the Renewing Health pilot sites shared their findings and recommendations with the follow-on project United4Health.

- **For healthcare providers:** to support the advance of standards by expressing their preference for standards-compliant products by purchasing them. Where appropriate, this may include procurement documents stating a preference for the use of specific standards and guidelines. Where possible, the requirement for interoperability with other existing systems should also be required. Where appropriate standards or guidelines are not available, remote monitoring pilots should contract with such suppliers who commit to convergence towards standards compliance.

- **For industry:** to bring products to market that meet guidelines and protocols where they exist, and to accelerate the development of guidelines and protocols where they do not (especially for those use cases that lend themselves to remote monitoring). Moreover, to understand that either at the interface between the gateway and aggregation point for analysis, or the interface between the aggregation point for analysis and the healthcare enterprise, messaging standards and eventually data standards will be demanded. They will need to decide if they will invest in implementing standards at the data source, or converting their information to standard designations at the interface to the customer. Lastly, they may be asked to integrate not just technology but clinical services on their side of the interface point.

- **For the remote monitoring projects and funders:** to be realistic about the state of the market(s), the status of applicable standards, and the industry’s capacity to deliver products that allow for subsequent scaling up within a project’s time frame.

To assist United4Health pilots in promoting the demand for standards, the IAT prepared a checklist document which could be included in the pilot sites’ procurement documents. Owing to the limited availability of products utilising the standards in the market, the document listed preferences for the use of the standards, rather than a mandatory requirement.

To make the case for industry, the IAT shared relevant information regarding the U4H pilots, their architectures and issues among the members of Continua and industry, with the message to accelerate the development of standards and protocols for use cases proposed by pilots.
Appendix A - References


Competitiveness and Innovation Framework Programme, ICT Policy and Support Program, Description of Work, UNIversal solutions in Telemedicine Deployment for European HEALTH care (United4Health), Grant Agreement Number 325215.
Appendix B - State of the Industry

The Industry Advisory Board consists of member of industries who are either members of the Continua Health Alliance, Cocir or GSMA. All organisations are classified as standards promulgation organisations, i.e. they recommend the use of standards based products; and if a standard is not available to meet a need, then they assist in developing a standard. The specific industries involved in the United4Health project are a subset of the healthcare industry, namely the medical device industry, the telecommunications industry, and the electronic / personal health record industry. United4Health is further constrained to focus on remote telehealth systems, which also includes the commercial wellness industry.

Telehealth is a fairly new technology in the healthcare industry, and by its heterogeneous nature can make adoption more difficult. According to Frost and Sullivan in June 2008, the European market for telehealth is projected to be “$240M with a projected compound annual growth rate of 12.5%”. However, the industrial barriers to adoption of telehealth were in order of priority: “lack of reimbursement, fast changing technology acting as a setback, privacy/confidentiality issues clouding the market, and resistance of the aged population to embrace the new technology”. Moreover, the market restraints for telehealth in Europe were listed as: “healthcare processes depending on the general practitioner for constant advice to patients, lack of pan-European standards, and high costs curbing the adoption rate”. This Industry Advisory Board can only indirectly affect healthcare processes and costs, but it can assist in identifying the technologies that are changing, recommend which and when to adopt those technologies, as well as help drive telehealth to be more standards-based and promote pan-European standards for telehealth.

Frost & Sullivan in 2013 had the following to say about the European market:

“Chronic disease management has been the focus of many recent health and home care innovations, offering a significant opportunity to retain independence, avert health complications, and reduce expenditures. Remote Patient Monitoring (RPM) technologies have enabled or supported many of these innovations. The RPM applications market in Europe in 2011 was worth $587.5 million. About 12.3 per cent of this amount was contributed by the telehealth applications as these are usually developed by the original equipment manufacturers (OEM) and limited third-party developers. The RPM applications market is estimated to grow at a rate of 5.0 per cent between 2012 and 2016…and is mainly driven by the increasing adoption of these technologies in order to reduce public expenditure on healthcare. Many global companies have set a strong foothold in the European market for RPM technologies”

Nevertheless, “the current economic scenario prevailing in Europe negatively affects the rapid adoption of technology. The struggling economies, such as that of Spain, are now adopting austerity measures to save the economy, which is expected to affect the healthcare market to a large extent. There is an increased focus on countries, such as the United Kingdom and Germany due to the growth momentum in their economies, as well as the government’s encouragement for these healthcare IT devices and solutions.”

There are ten countries involved in the United4Health programme: Czech Republic, Finland, France, Germany, Greece, Italy, Norway, Slovenia, Spain and United Kingdom. According to the previously referenced Frost and Sullivan 2008 report,
the following vendors have the primary market share for telehealth products in the countries listed. Overall, the report also mentions that 60% of the telehealth market is owned by the services industry (telecommunications) and 40% is owned by the device manufacturers. Additionally, there is no one market leader which leads to intense competition at European level to gain market lead.

Table 6: Leading Telehealth Vendors listed by Country - 2008

<table>
<thead>
<tr>
<th>Country</th>
<th>Telehealth Vendor</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>Philips Healthcare, Biotronik, Card Guard AG, and Viterion Telehealthcare LLC</td>
</tr>
<tr>
<td>Germany</td>
<td>Philips Healthcare, Health Hero Network (now Bosch), BodyTel Scientific Inc, and Docobo</td>
</tr>
<tr>
<td>Greece</td>
<td>Not analysed</td>
</tr>
<tr>
<td>Italy</td>
<td>Biotronik, Health Hero Network (Bosch), Tunstall Healthcare Group, and Philips Healthcare</td>
</tr>
<tr>
<td>Spain</td>
<td>Philips Medical Systems, Aerotel Medical Systems, CardGuard AG and Viterion Telehealthcare LLC</td>
</tr>
<tr>
<td>Scandinavia – Finland, Denmark, Norway, Sweden</td>
<td>Philips Medical Systems, Biotronik, CardGuard AG, and Health Hero Network (Bosch)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Philips Healthcare, Docobo, Tunstall Group, Health Hero Network (Bosch), and Aerotel Medical Systems</td>
</tr>
</tbody>
</table>

Of the companies listed in the table above, Philips Healthcare, Health Hero Network (now Bosch) and Tunstall Healthcare Group AG are members of the Continua Alliance, while Philips Healthcare is the only participating member in IHE-PCD.

There were some changes, mainly consolidation and dominance by the global vendors, in the market in 2013 as per Frost & Sullivan with the participants shown in the table below:

Table 7: Telehealth Vendors listed by Country - 2013

<table>
<thead>
<tr>
<th>Country</th>
<th>Telehealth Vendor: Major dominant participants; other notable participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>Philips, GE Healthcare, Honeywell; Aerotel, Tynetec, Polycom</td>
</tr>
<tr>
<td>Germany</td>
<td>Bosch, Tunstall, Philips: Aerotel, Bodytel</td>
</tr>
<tr>
<td>Greece</td>
<td>Not analysed</td>
</tr>
<tr>
<td>Italy</td>
<td>Philips, GE Healthcare, Honeywell; Aerotel, Tynetec, Polycom</td>
</tr>
<tr>
<td>Spain</td>
<td>Philips, GE Healthcare, Honeywell; Aerotel, Tynetec, Polycom</td>
</tr>
<tr>
<td>Scandinavia – Finland, Denmark, Norway, Sweden</td>
<td>Philips, GE Healthcare, Honeywell; Aerotel, Tynetec, Polycom</td>
</tr>
</tbody>
</table>
Country | Telehealth Vendor: Major dominant participants; other notable participants
--- | ---
United Kingdom | Telehealth – Docobo, Philips, Tunstall; Telecare – Tynetec, Chubb, Cirrus; Aerotel, Bosch

Of the companies listed in the table above, BodyTel, Bosch, GE Healthcare, Philips, Tunstall and Tynetec are members of the Continua Alliance, while GE Healthcare and Philips are the only participating members in IHE-PCD.

As part of the research for this deliverable, the pilot sites were asked who the prevalent vendors in telemedicine were in their regions (who they knew as the prevalent vendors). The table below lists the pilot sites which provided their answers.

<table>
<thead>
<tr>
<th>Region/Country</th>
<th>Prominent Telehealth Vendors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spain, Basque Country</td>
<td>Tunstall Ibérica SA, Saludnova S. Coop, Telefónica</td>
</tr>
<tr>
<td>Norway</td>
<td>Scan Med (for medical devices); Dignio, MediSat (both for telehealth services)</td>
</tr>
<tr>
<td>United Kingdom, Scotland</td>
<td>DIASEND, Medvivo, Simple Telehealth (Florence) via MediaBurst Ltd and NHS Stoke GGC, Philips Ltd (all telehealth services)</td>
</tr>
<tr>
<td>United Kingdom, Wales</td>
<td>Solcom (medical devices); 3G and Simple Telehealth (Telehealth services)</td>
</tr>
</tbody>
</table>

### B.1 Continua Certified Products

For a list of devices on the market that are Continua certified see http://www.continuaalliance.org/products/product-showcase.
## B.2 Device Enterprise Communication (DEC)

Device Enterprise Communication (DEC) IHE-PCD-01 as of European Connectathon 2010, 2011 and 2013

**Table 9: Device Enterprise Communication**

<table>
<thead>
<tr>
<th>Device Enterprise Communication</th>
<th>Device Observation Consumer</th>
<th>Device Observation Filter</th>
<th>Device Observation Reporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>B. Braun Medical</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>CapsuleTech Inc.</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Cardinal Health</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>CareFusion</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Cerner Corporation</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Draeger Medical Systems, Inc.</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Epic Systems Corporation</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Fresenius Kabi</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Hospira</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Live Data</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Philips Medical Systems</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>RVC bv</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Spacelabs Healthcare</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Surgical Information Systems</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Welch Allyn, Inc</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>