



# UNiversal solutions in TElemedicine Deployment for European HEALTH care

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### Abstract

This document presents the first results of the VigiSanté project.

### Key Word List

Hypertension, monitoring, evaluation protocol, satisfaction.

## Executive Summary

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This intermediate report presents the VigiSanté project, its evaluation protocol and preliminary results regarding the acceptability of the project by patients, doctors and companies. VigiSanté is a pilot project combining screening for hypertension in companies, supporting by a medicalised platform, in connection with general practitioners (GPs) and telemonitoring of hypertensive patients at home.

The assessment is based on the comparison of two groups: an intervention group, which is the VigiSanté group, and a control group, which is divided into two parts, medical data and health expenses respectively. Medical data were collected by a physician from medical records (retrospective data of 145 patients). For the economic data, the National Health Insurance Fund database was used to collect the medical consumption of a sample of hypertensive patients in the North of France and the retrospective consumption data of the VigiSanté patients.

In order to measure the acceptability of the VigiSanté service, three surveys regarding satisfaction and acceptance of remote monitoring in the context of hypertension have been implemented for patients, GPs and companies involved in the programme.

The implementation of a service such as VigiSanté met the expectations of patients and health professionals. From the patients' point of view, the medical information present in eHealth programmes can improve diagnosis and treatment. 59% of patients involved in the project experienced an improvement in their health, 80% were satisfied with the follow up of their hypertension monitoring and support, and more than 80% of attendees would recommend it to relatives. From the physicians' point of view, the implementation of such a service strengthens the role of the GP. The study shows that for 69% of GPs, the integration of patients into VigiSanté allowed global health benefits, including on blood pressure. The cutting edge of the study is the empowerment given by the VigiSanté project, that is to say giving patients the means to become responsible for his/her own health.

## Change History

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### Version History:

1.3 27<sup>th</sup> November 2013  
1.4 5<sup>th</sup> December 2013  
2.0 13<sup>th</sup> December 2013      Version for issue

### Version Changes

1.3 Draft for review.  
1.4 Minor changes following review  
2.0 Version for issue

### Outstanding Issues

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# 1. Introduction

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## 1.1 Purpose of this document

This document contains the intermediate trial report for U4H pilot in France. It uses the approach based on MAST methodology.

VIGISANTE is a project developed in response to a call for projects by the French Ministry of Industry, in connection with the Ministry of Health, on the management of chronic diseases by telemedicine. It concerns hypertension and associated risk factors. 4500 employees were screened and 669 patients included in this monitoring programme for hypertension.

The objective of WP9 is to test in real-life conditions the set of telehealth services which have been selected for the management of patients suffering from hypertension. Hypertension has a significant impact on factors of cardiovascular risk. Remote monitoring tools through telehealth can reduce healthcare spending and absenteeism. VIGISANTE is a pilot project combining screening for hypertension in companies, supporting by a medicalised platform, in connection with general practitioner (GP) and telemonitoring of hypertensive patients at home. The pilot focuses primarily on the Nord-Pas-de-Calais region (North of France).

VIGISANTE is quite specific in the United4Health project. The inclusion period started in October 2011 and ended in April 2012 with a target of a mean follow-up of 12 months.

## 1.2 Structure of the document

Section 2 contains information for MAST Domain 1: The health problem and the telemedicine application.

Section 3 contains information on Domains 2 and 3: Safety and clinical effectiveness.

Section 4 contains information and data on Domain 4: Patient perspectives. This is the main part of this report because of the availability of the data at this point of time.

Section 5 contains information and data on Domain 5: Economic aspects.

The MAST Domains 6 and 7 couldn't be assessed for VIGISANTE.

Section 6 discusses transferability assessment.

Note that many results from the pilots are not available for this Intermediate Pilot Evaluation, and will be described in the Final Pilot Evaluation. To preserve the structure of this document as a stepping stone towards the Final Pilot Evaluation, the section heading for the results has been included, with the text: "This section will be completed in the Final Trial evaluation". Also included are some tables that will be completed as part of the final evaluation.

### 1.3 **Glossary**

**GP**            General Practitioner

**ICT**           Information and Communications Technology

## 2. Domain 1: Description of the health problem and characteristics of the application

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### 2.1 The health problem of the patients

Blood pressure (hypertension) is the leading chronic disease in the world. It increases the risk of accidents, stroke, coronary heart disease, heart failure, kidney failure and cognitive impairment. Antihypertensive treatment aims to reduce cardiovascular complications. In France, the number of patients treated for hypertension is estimated at around 12 million<sup>1</sup>.

A patient is considered hypertensive if he has a blood pressure higher than or equal to a target threshold. Hypertension is defined by a systolic blood pressure  $\geq 140$  mmHg and / or diastolic blood pressure  $\geq 90$  mmHg. The management of hypertension is dependent on the severity of hypertension and associated risk factors.

According to Wagner et al. (2008), the prevalence of hypertension in France is 34.8% at the threshold of 140/90 mm Hg in the age group of 35-64 years. The article also highlights a gender gap, because its prevalence is higher among men (41.8%) than women (27.8%).

In France, 20% of known hypertensive patients are not treated, and 50% of treated hypertensive patients are not controlled.

### 2.2 Burden of the disease

In 2009, in the Nord-Pas-de-Calais Region (North of France), 6,734 new cases of hypertension were detected. There were also 5,663 new cases of coronary heart disease and 2,595 stroke cases. These diseases are related to vascular diseases including hypertension. 187,552 people with an illness related to or induced by hypertension are considered as long term affected patients. These figures obviously do not include people who were not screened. Indeed, one out of two hypertensive patients does not know he is hypertensive.

In the Nord-Pas-De-Calais region, 6 of 10 hypertensive individuals enter the classification at high cardiovascular risk. Mortality from this type of disease is significantly higher in Nord-Pas-De-Calais than in France - it is 25% higher than the national average.

### 2.3 Current management

According to the French National Authority for Health, the practice guidelines are:

- Confirm the diagnosis of hypertension.
- Conduct an initial assessment.;

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<sup>1</sup> French National Authority for Health



- Organise an information and consultation announcement of hypertension.
- Set-up lifestyle changes (and monitoring).
- Control of blood pressure in the first six months.
- Focus on five classes of antihypertensive drugs that have demonstrated prevention of cardiovascular complications.
- Individualise the choice of first antihypertensive treatment.
- Combine two active ingredients.
- Ensure good tolerance.

## 2.4 Use of the technical application

Several technical applications were used depending on the timing of the project and the user's profile. The project was divided into two phases.

Phase 1 - Screening of employees in companies in order to identify hypertensive employees.

- Technical applications for nurse in charge of screening:
  - PC + 3G Card / firms' Internet connection).
  - Medical devices: sphygmomanometer + mobile ECG.
  - Creation of Vigisante patient records (connection to the remote Innovelan application by the nurse - no specific installation on the workstation).
- Access to an online-coaching programme ("Mangez juste, bougez plus") focused on nutrition to improve quality of life. A personal login and initial password were given at the end of the meeting with the nurse in charge of screening in a company only to people who were not diagnosed with hypertension.

Phase 2 - Follow-up of hypertensive employee at home (Figure 1):

- Technical applications for hypertensive employee at home:
  - Medical devices: sphygmomanometer + balance / pillbox (if necessary) + interconnecting base.
  - Access to the programme portal ([www.programmevigisante.fr](http://www.programmevigisante.fr)) + personal login and initial password for access to personal file, which is shared with nurses of the medicalised platform and GP - if he agreed.
  - Phone number of the medicalised platform.
- Technical applications for GP (who agreed to join the programme):
  - Access to the programme portal ([www.programmevigisante.fr](http://www.programmevigisante.fr));
  - Personal login and initial password for access to his patients' files.
  - Phone number of the medicalised platform.
- Technical applications for the platform nurses:
  - Access to the programme portal ([www.programmevigisante.fr](http://www.programmevigisante.fr)).
  - Personal login and initial password for access to patient's records.

The medicalised platform was a key success factor of the project. It was in charge of:

- Following up the medical data collected at home (blood pressure, weight and heart rate) in association with the GP.
- Coaching people to help them set up healthy behaviours (nutrition and physical activity).
- Improving hypertension awareness by giving information and answering any questions (therapeutic education).
- Providing user's assistance (hotline).
- Providing data for reporting, e.g. follow-up of active patients, reasons for leaving, etc.

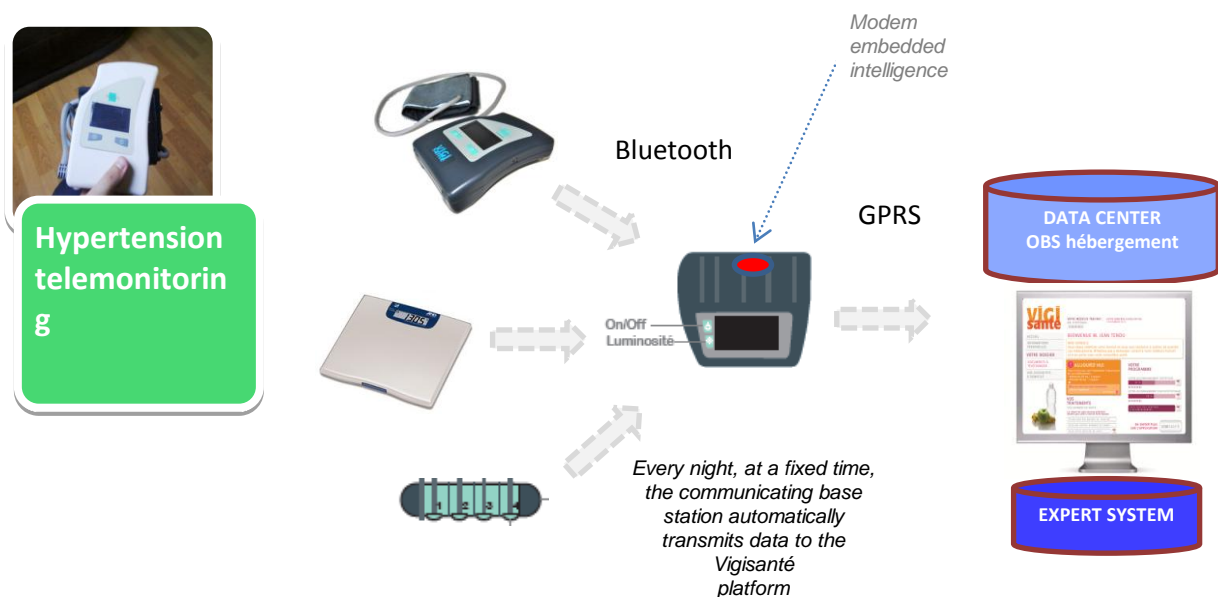


Figure 1: Medical data collection from home to web

## 2.5 Technical characteristics

The main principal characteristics of the VigiSanté system are based on the Machine-to-Machine concept (Figure 2).

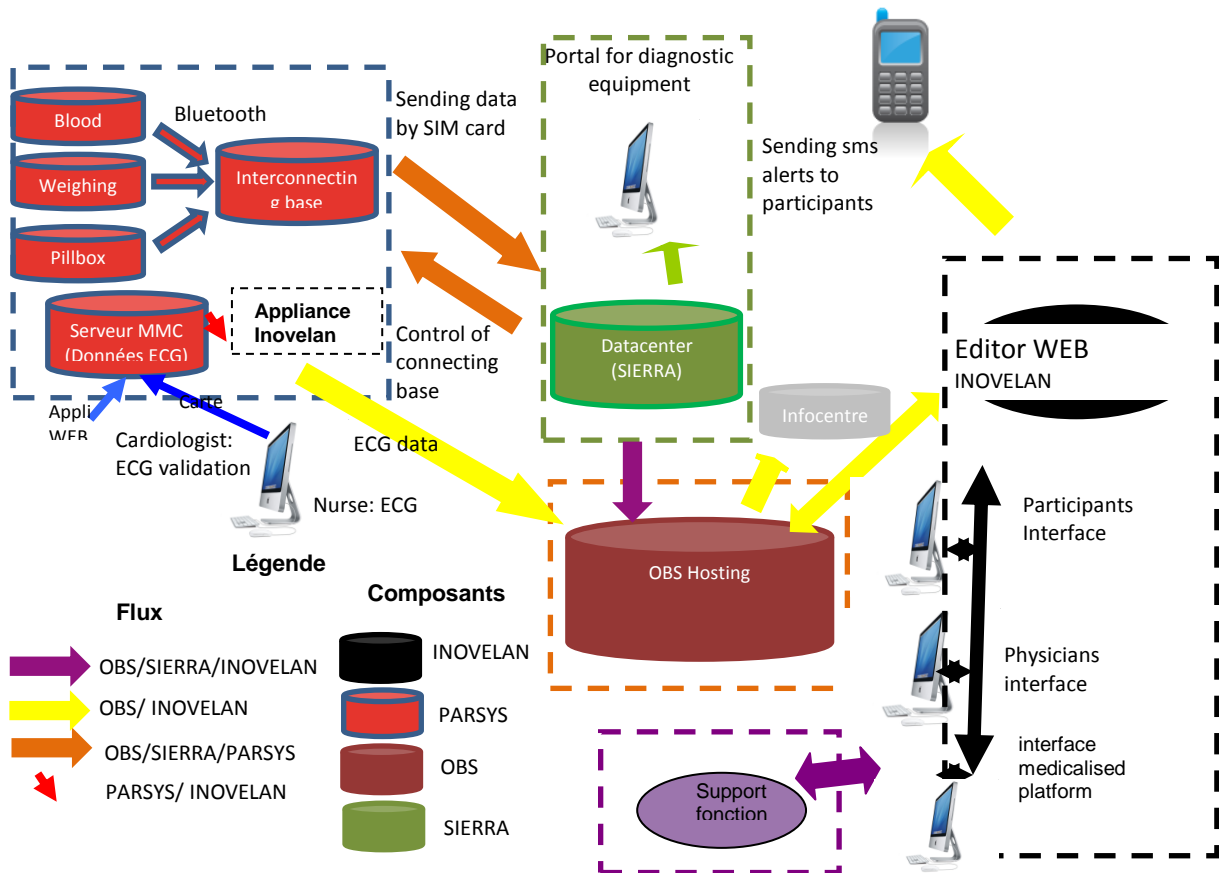


Figure 2: VigiSanté scheme

The link between medical devices (blood pressure, balance and pillbox) and the base is provided by a Bluetooth connection.

The flow of information (blood pressure, medication, weight) represents a volume of 200 bytes / day / base.

## 2.6 Requirements

Equipment and supplies needed to use the application:

- Prerequisite for inclusion in the program:
  - Required: telephone (fixed and / or mobile).
  - Optional (but highly recommended for optimal use of the programme): PC, Internet connection and active e-mail address.
- No settings / configuration tool was needed: web application. The only requirements = login + password.

### Training needed for the users (patient and staff)

Preliminary remark: design of patient records made on the basis of focus groups (representatives of patients and health professionals) and co-construction of Inovelan folder / medicalised platform.

Training for hypertensive patients who joined the programme:

- **Screening (if patient agreed to join the programme):** medical devices instructions given with the medical devices + getting starting guide for the medical devices.
- **Follow-up at home:**
  - Online download of a getting starting guide for medical devices, portal login guide and navigation guide for the personal file (on VigiSanté portal).
  - User's assistance (hotline) from the medicalised platform, including technical assistance if necessary.

Training for GPs who joined the programme:

- Online download of a getting starting guide for medical devices, portal login guide and navigation guide for the personal files (on VigiSanté portal);
- User's assistance (hotline) from the medicalised platform, included technical assistance if necessary.

Training for medical staff (nurses and doctor) of the platform:

- Preliminary training:
  - Overview of the programme, process and speech drafts for each interaction with patients and/or GPs.
  - Surf the patient's records and tasks / alerts for medical staff.
- Five focused training sessions for nurses:
  - Ethics (duration: 2 hours).
  - Motivational interview (duration: 2.5days / nurse).
  - Information system and security (duration: 2 hours \* 2 sessions).
  - Nutrition (duration: 1 day).
  - Directions for phone coaching (duration: 1 day).

For medicalised platform: assistance for any question from project team provided by Malakoff Mederic (project leader and responsible for interaction with the platform).

### **3. Domain 2 and 3: Safety and clinical effectiveness**

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#### **3.1 Methods: Trial design**

The design trial is an observational study: “with” or “without” telemedicine.

We have two groups: an intervention group which is the VigiSanté group, and a control group, which is divided into two parts, medical data and health expenses respectively. For the medical data, a physician collected data from medical records (retrospective data for 145 patients). For the economic data, we used the National Health Insurance Fund database in order to have the medical consumption of a sample of hypertensive patients in the north of France, and the retrospective health consumption data of the VigiSanté patients.

#### **3.2 Methods: Participants**

The inclusion criteria were:

- Age > 18 years.
- Employees of companies benefiting from group health coverage with one of the three partner institutions.
- Confirmation of the existence of hypertension through blood pressure self-measurement three times a day in a week, or through a series of monitoring during a period of time defined in the medical specifications of the VigiSanté project.

The exclusion criteria were:

- ECG of patient revealed an abnormal heart rhythm.
- Physicians and/or the patient decline to participate.
- Hypertension was not confirmed.

#### **3.3 Methods: Interventions**

The main clinical criterion is the systolic and diastolic blood pressure.

The other clinical indicators are: heart rate, SatO2 (%), weight, ECG (rhythm, QRS), comorbidity, medications and adherence rates.

#### **3.4 Methods: Outcomes**

Depending on the enrolment date, the duration of follow up varied from 9 to 18 months (longitudinal data).

According to the Information System of VigiSanté, three main demographic data were collected: age, gender, and marital status. Two other bits of information concerned their technology: having a PC and being an Internet user.

Clinical data were: measurement of blood pressure and heart rate, and if required, weight and medication compliance.

Economic data were: investment and exploitation data, as well as health expenses related to HTA.

### 3.5 **Methods: Statistical methods**

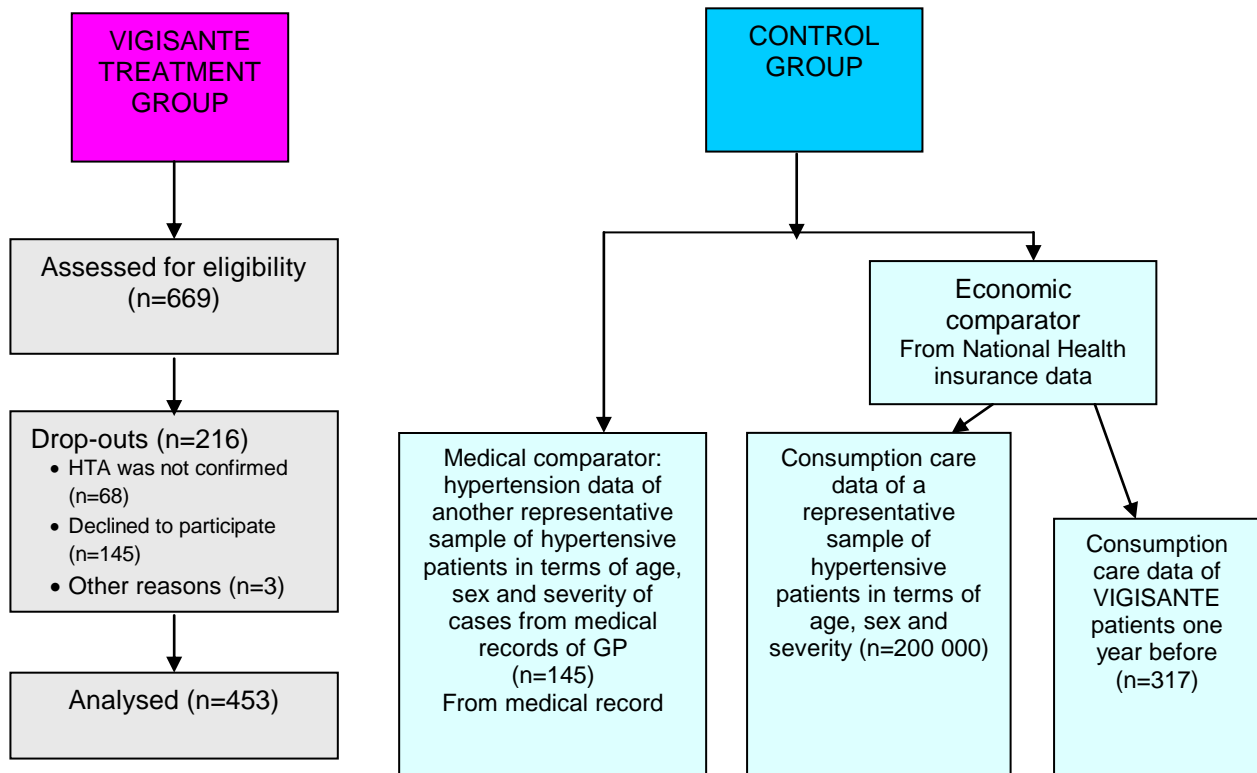
The quantitative data is analysed through statistical software (R or SAS® or SPSS®). Quantitative and qualitative analyses evaluate the project itself and its various components.

The data from the information system are organised around a relational schema database for the extraction and implementation of processing algorithms.

### 3.6 **Results: Participant flow**

Patient recruitment was conducted by VIGISANTE support function in partnership with the departments of human resources supported by information campaigns and promotion. Among the 4,500 screening appointments made, 669 salaried staff were assessed for the project; 453 were included, and were active until the end of the programme. Employees included in the study are those for whom the existence of hypertension has been confirmed, either by self-measurement of blood pressure three times every morning and evening over a week, or by a series of measurements during a period of time defined by medical specifications. Patients were monitored during 9 - 18 months; the end of the trial was scheduled for April 2013.

Figure 3 shows the flow diagram.


**Figure 3: Flow diagram**

### 3.7 Results: Baseline data

Table 1 presents the demographic characteristics of the intervention group (VigiSanté) and the medical control group.

**Table 1: Baseline demographic characteristics**

Measurement	Intervention	Control
Sample Size (n)	650	145
Age	48.84 (sd=8.12)	51.82 (sd=9.2)
Men (gender)	66,46%	62,07%
Smoker – yes/total(%)	47,25%	22,86%
Alcohol		
Daily one glass	18,87%	11,81%
Daily two glass	5,50%	8,33%
Daily three glass	2,23%	6,25%
Daily more four glass	1,34%	4,17%
Once per week	39,08%	31,25%
Less than once/month	32,84%	38,19%

Measurement	Intervention	Control
Height in cm	172,75 (sd=9,93)	171,32 (sd=12,44)
Weight in kg	83,94	90,84 (sd=18,02)
Comorbidity		
Heart disease	40,46%	66,21%
Diabetes	6,15%	13,79%
Renal disease	8,15%	1,38%

### 3.8 Results: Estimation of outcomes

This section will be completed in the Final Trial evaluation.

**Table 2: Results of analyses**

Outcome	Intervention		Control		Mean difference after 6 month between groups (CI 95%)
	Baseline	After 6 month	Baseline	After 6 month	
Blood pressure	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (CI to CI)
Care consumption					
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (CI to CI)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (CI to CI)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (CI to CI)

### 3.9 Discussion of findings

This section will be completed in the Final Trial evaluation



## 4. Domain 4: Patient perspectives

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### 4.1 Aim of the study and the instrument used

Three surveys, regarding satisfaction and acceptance of remote monitoring focused on hypertension, have been conducted with patients, GPs and the companies involved in the programme.

Regarding the patients' and the physicians' surveys, there were two objectives:

- to assess the use and satisfaction;
- to understand the acceptance model.

Finally, the companies' survey aimed at understanding the determinants of the VIGISANTE membership.

The three questionnaires were carried out by Telecom Bretagne. The different parts of the questionnaire were:

- Perceived health for patients.
- Use of ICT and ICT for health.
- Opinion of the portal.
  - ease of use;
  - resents on monitoring;
  - frequency of use;
  - satisfaction;
  - global quality;
  - recommendations.
- Companies' reasons to participate in Vigisanté.
- Policy implementation in the company's occupational health.
- Demographic profile.

### 4.2 Data collection

The surveys were conducted between October 2012 and June 2013. They were made by mail (4.2%), Internet (78.2%) and telephone (17.6%). For employees who left before the end of the programme, the study was conducted in two stages: a first session in October 2012 and a second session in January 2013.

For people who were there at the end of the trial, the survey was carried out digitally in May 2013.

As a result, we collected:

- For patients: 57 answers from patients who left before the end of the programme (total of 216 exits) and 132 responses of patients who finished the VigiSanté protocol, out of 453 included in the programme. That is 189 answers all in all.

- For physicians: 52 responses out of 572 GPs.
- For companies which implemented VigiSanté: 25 responses out of 50 companies.

## 4.3 Results

### 4.3.1 The patients' perspective

The satisfaction survey was based on a sample of 189 patients. We included in this analysis two groups: one group with the people that left before the end of the programme, the other group with the employees who remained until the end. The first group consisted of 57 patients (out of 216) who left before the end of the program. The second group was composed of 132 patients who completed the VigiSanté protocol (out of 453 included in the programme).

The sample was composed of 67.6 % men and 32.4 % women. The distribution by age groups was as follows:

- 18 – 25 years: 1,7 % ;
- 26 – 35 years: 6,2 % ;
- 36 – 45 years: 21,8 % ;
- 46 – 55 years: 39,1 % ;
- 56 – 65 years: 31,3 %.

73.4% of the individuals in the cohort were married.

#### 4.3.1.1 The patient and his health

The importance of these questions is to identify how the hypertensive employee perceives his health and access to care. Of all those interviewed, 6.9% perceived their health as excellent, 17.6% in very good health, 66.5% healthy, 6.91% in poor health (Figure 4).

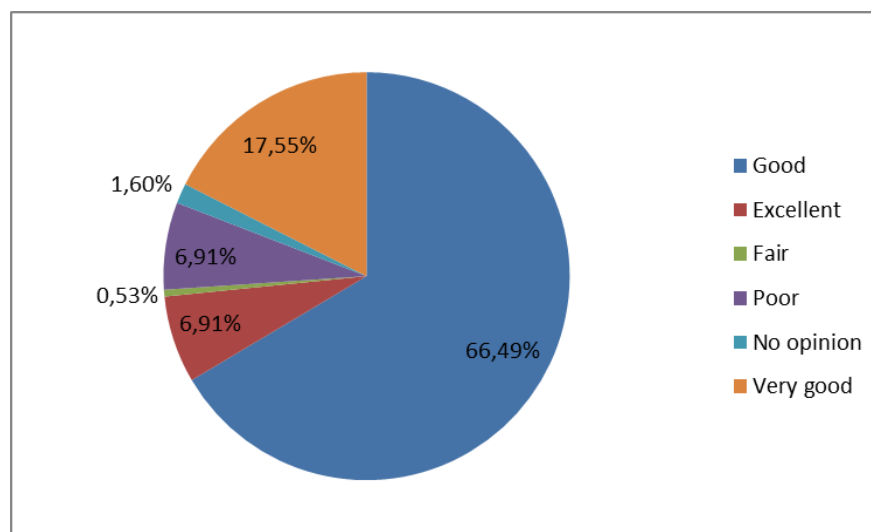
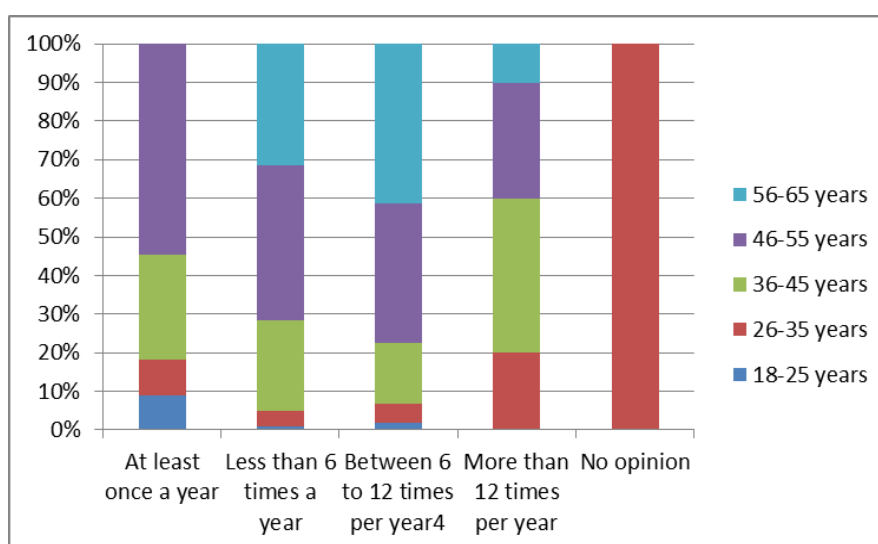


Figure 4: How do you assess your health?

On visits to the GP, 56% of the interviewed persons went there fewer than six times per year, while 32% saw their GP between 6-12 times a year. Among the patients who went there fewer than six times per year, we found that older people from 46 to 55 are the majority (40.4%), while those who are older than 56 years old constituted at least 31%. The number of visits between 6 and 12 times per year were represented by those aged 56-65 years old (41.4%), followed by 46-55 years old (36.2%) (Figure 5).



**Figure 5: Data on age and the number of visits to the doctor**

Regarding the distance to access patient care, we observed that the GP's office was located at less than 5 km for 71% of respondents, while the specialist office was at less than 10 km for 51.6% of those interviewed. Finally, access to the nearest hospital was located less than 10 km for 56% of respondents.

#### 4.3.1.2 The use of ICT by patients

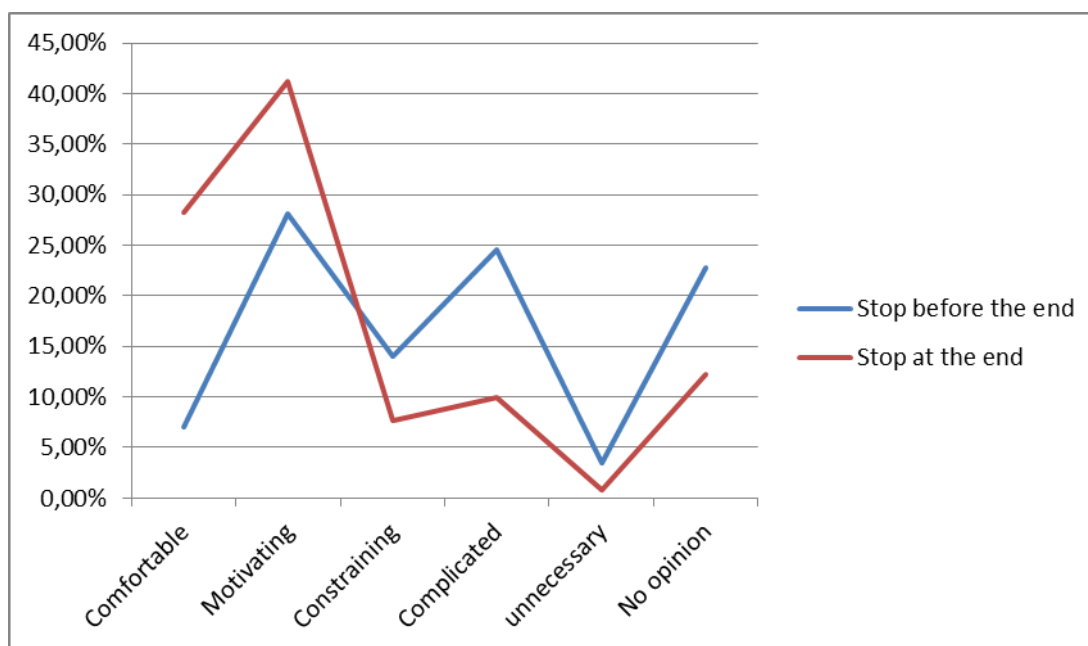
In the context of the use of ICT, we observed that 94.7% of respondents had a computer at home. Moreover, 60.6% of individuals had an average weekly use between one and seven hours, and 17.6% used the computer more than seven hours per week. In addition, 96.3% of respondents had an Internet connection. More specifically concerning the use of the Internet, we saw that 73.4% of the respondents have used the Internet for over five years.

60% of respondents used the Internet to search for health information. It appeared that women (72.4%) were more active in seeking information than men (57.9%). In addition, those aged 46 and up did more Internet searches. This health information search occurred at a frequency of at least once a month for 34% of respondents. Moreover, we noted that more than two thirds of people who used the Internet for medical information looked for between one to three types of information. The distribution of information taken from the Internet was:

- 29.8% of people made inquiries about lifestyle;
- 17.6% learned about the use of drugs;
- 22.9% were informed about a specific medical topic (pain, cancer diagnosis, etc.); and
- 22.9% researched for information on specific diseases (hypertension, diabetes, heart failure ...).

#### 4.3.1.3 Patients' views of the VigiSanté portal

74% of participants were satisfied with the use of the VigiSanté portal. We found that out of the population of employees, 69% found the portal reassuring and motivating. However, 42% of patients who left before the end the programme found the trial constraining, complicated and unnecessary, and 22% were undecided (Figure 6).



**Figure 6: Patients evaluation of the VigiSanté portal**

We found that navigation of VigiSanté portal was easy for 64.36% of users, though 17% had a negative opinion on the ease of use. However, the use of VigiSanté portal required an effort of concentration for 41% of participants. In addition, 56.4% found it easy to find information within the VigiSanté portal. And finally, 46% of participants did not need help using the VigiSanté portal.

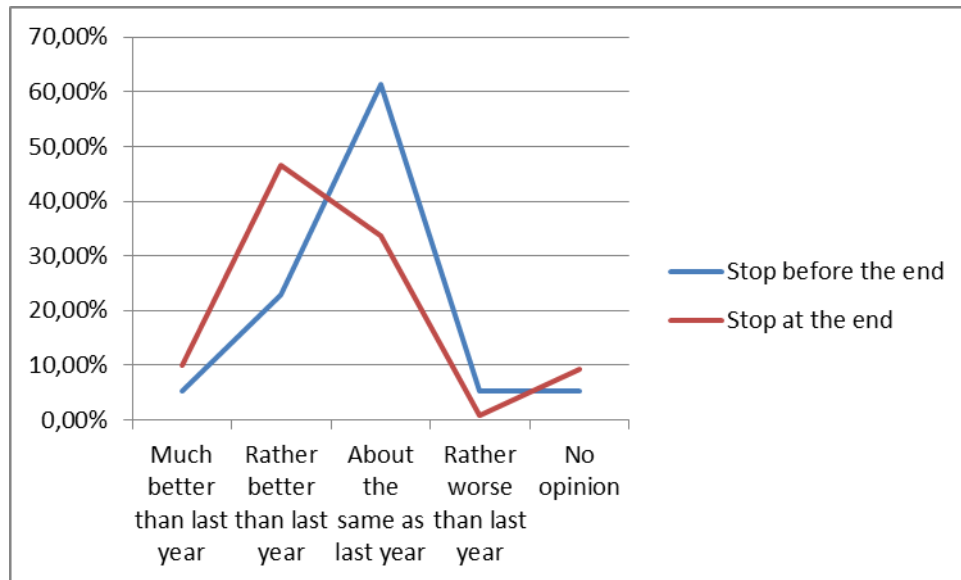
#### 4.3.1.4 Patients' views on the monitoring of hypertension and support of the system

Regarding the monitoring and support of hypertension proposed by VigiSanté, we observed that 80% were satisfied with the monitoring and support. We found that 58% of those who left before the end the trial were satisfied with the monitoring and support offered by VigiSanté, compared with 90% of those who used VigiSanté until the end.

Nurses were attentive and available for 86% of respondents. 75% of participants believed that the frequency of use of their medical device seemed appropriate. 78% felt that the medical device was easy to use. And finally, 81% were satisfied with the sessions conducted by the nurses. We observed that of the patients followed in VigiSanté project, 84% enjoyed the remote monitoring compared to conventional care.

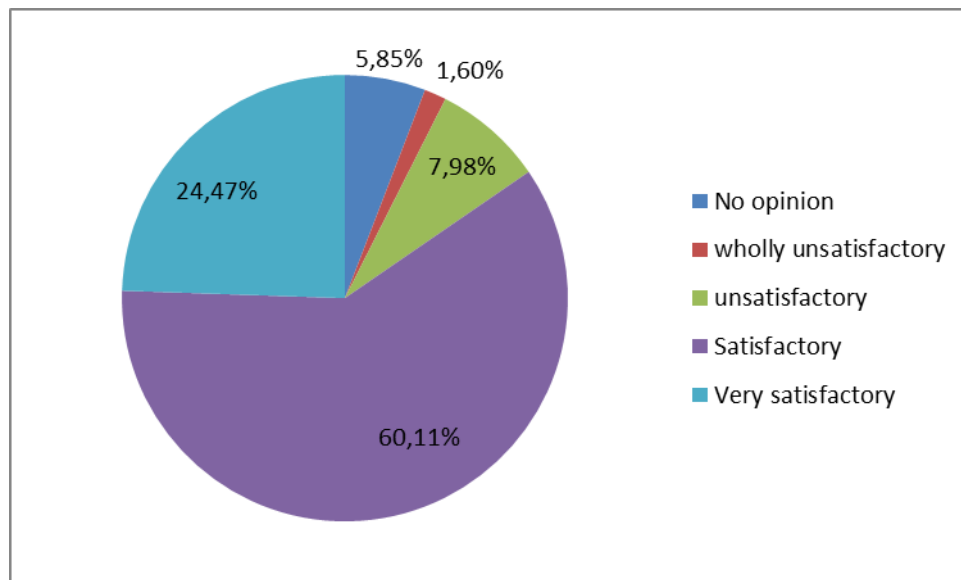
It is important to take into consideration the patients' perception of their current health status, compared that of the year before (Figure 7). We noted that for those who remained until the end of the programme, 47% felt they were healthier than last

year. In contrast, only 28% of those who left the programme before the end felt in better health. 61% of employees who stopped the treatment protocol before the end found their health as "about the same" as last year.



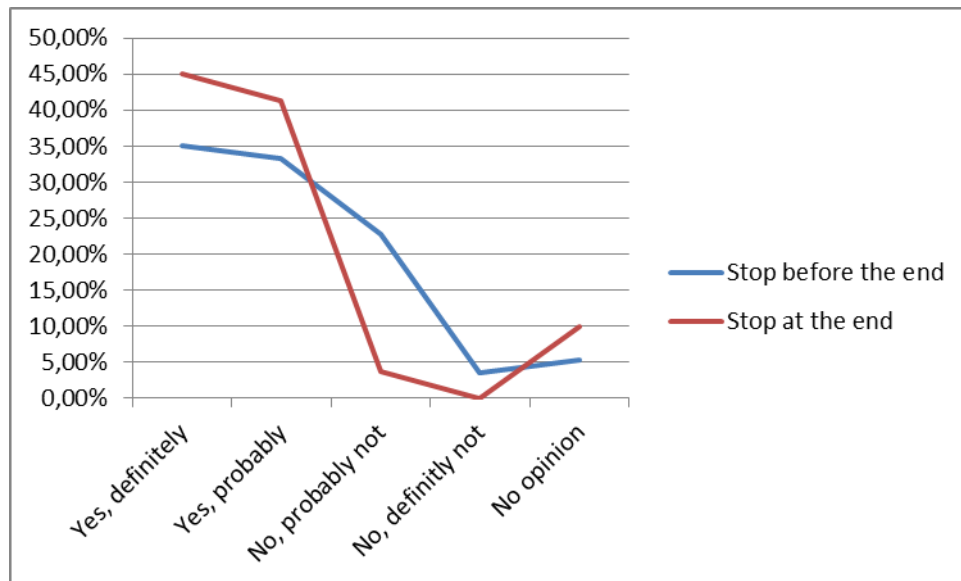
**Figure 7: Compared to last year at the same time, how do you assess your current health status?**

Finally, we observed that 85% of participants perceived the quality of the VigiSanté programme as good to very good (Figure 8). In addition, 81% are willing to recommend VigiSanté to friends or family.



**Figure 8: Perception of the overall quality of VigiSanté**

We noted that of the population of workers who stayed to the end of the trial, 96% recommended VigiSanté, as opposed to 68% of the employees who stopped before the end (Figure 9).



**Figure 9: Would you recommend the VigiSanté program to your family or friends?**

#### 4.3.2 GPs' perspective

The VigiSanté programme for GPs consists of a VigiSanté portal that summarises all the information recorded by the different medical devices, and also provides summaries of the various meetings with nurses and doctors of the platform. 575 GPs were contacted. 227 were identified as having given their total agreement (acceptance for monitoring the portal), 97 were identified as having given a partial agreement (refusal monitoring the portal), and seven doctors were identified as having refused the participation of their patients in the programme. For the remaining 244 physicians no information was provided. Our study focused on a sample of 51 respondents, composed of 61.9% men and 38.1% women. The distribution of age groups was as follows:

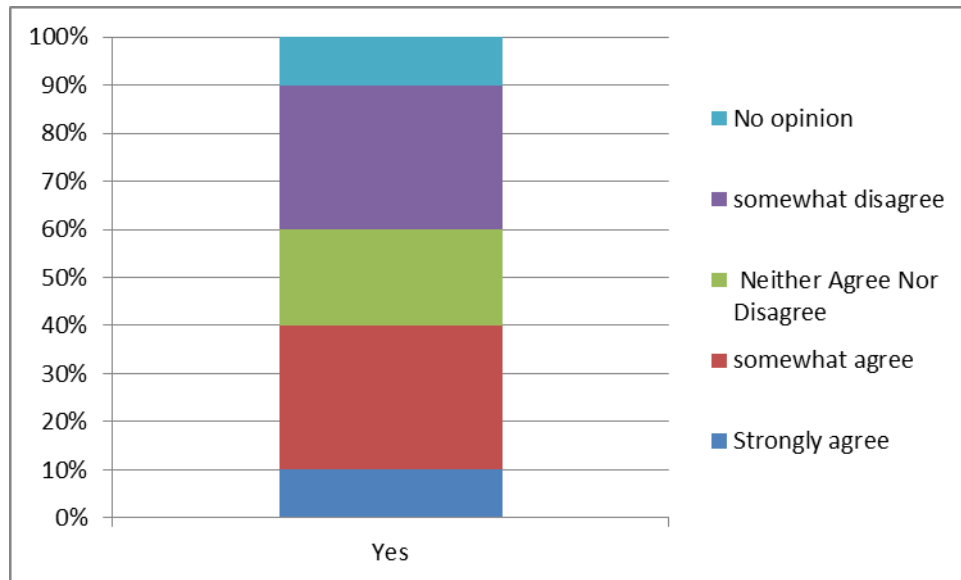
- 36-45 years: 32.9%;
- 46-55 years: 38.6%;
- 56-65 years: 28.6%.

According to the age pyramid, we saw that the population of GPs in the territory of the Nord-Pas-de-Calais region was: 78% men and 22% women.

The GPs' offices were well equipped with ICT: 96.2% had a PC, 85.5% of practices had medical software, and 85.5% had an Internet connection. The physicians' main motivations for participating in the VigiSanté programme were that they expected it to benefit patients (92.2%), or because it was a public health issue (13.7%), and finally because it optimised the time of a medical consultation (2%).

Only 19.6% of GPs used the VigiSanté portal. Looking at the distribution by gender, 20.5% of male GPs used it as compared to 16.7% of females. Looking at the distribution by age and gender of GPs who answered "yes" to the use of the VigiSanté portal, we saw that the men aged 36-45 years (62.5%) were the largest users. For women, the distribution was for 50% in the age group 36-45 years and 50% in the age group 46-55 years.

The navigation and search for information on the VigiSanté portal was not so easy for 88.98% of GPs. We saw that 40% of the GPs surveyed who used the VigiSanté portal believed it allowed them to take better care of their patients (Figure 10).



**Figure 10: Do you think that the VigiSanté system permit you to better manage your patients?**

The implementation of the VigiSanté programme slightly changed the care provided by doctors to their patients suffering from hypertension. Essentially, it was a change in behaviour on the patients' part, according to 64.7% of physicians. Changed behaviours observed by health professional's included:

- diet (17.7%);
- healthy lifestyle (19.6%);
- medication compliance (15.7%).

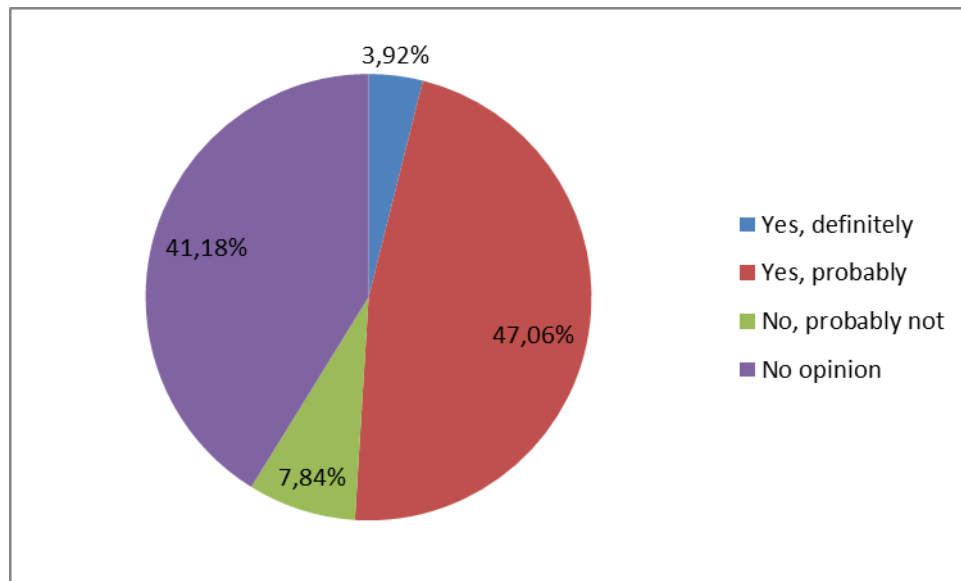
76.5% of patients told their family doctor that they were participating in the VigiSanté programme. For 90.2% of the physicians surveyed, consultation time was not changed. The consultation period for a patient followed by VigiSanté was longer only in 9.8% of cases. Finally, the frequency of consultation did not increase for 84.3% of respondents.

According to 39.2% of GPs, the VigiSanté programme facilitated access to care. In addition, the integration of a patient into the VigiSanté programme allowed doctors (68.6%) to see benefits in the overall health of the patient and on blood pressure.

Finally, we can say that the VigiSanté portal was seen by GPs as too complicated; they did not have the time to learn how to use it because of their busy schedule.

However, the VigiSanté programme was perceived by physicians to improve patient healthy lifestyle (47.1%), improve patient empowerment (25.5%), and improve patient compliance (15.7%). In addition, 51% of GPs were willing to recommend VigiSanté to other doctors (Figure 11).





**Figure 11: Will you recommend VigiSanté?**

### 4.3.3 Companies' perspectives

50 companies initially took part in VigiSanté. These companies were organised as follows: 4% had fewer than 20 employees, 66% had between 20 and 499 employees, and finally 30% had more than 500 employees. The average size of the companies present in VigiSanté was 498 employees. The distribution of employees was represented by 72% staff and 28% managers. Of the companies in this sample, 24% had a regional client base, 20% national clientele and 52% international clientele. In addition, 68% of companies in the sample had hourly employees on shift works.

The firms in the survey signed contracts with different types of provident institutions. 52% of the contracts combined complementary health and welfare, and 32% subscribed to pension contracts. A health service inter-working organisation (SSTI) managed employees' occupational medicine for 91.3% of companies. Occupational medicine participated in the development or implementation of a policy in 48% of companies. Apart from VigiSanté, companies included in the survey implemented the following actions for health:

- 68%: prevention of occupational hazards;
- 12%: a health barometer at work;
- 48%: prevention of psychosocial risks;
- 60%: public health actions (vaccination, screening, blood donation, ...);
- 12%: a health and safety forum.

96% of companies said they had actively participated in the deployment of the VigiSanté programme. The main motivations to participate in the VigiSanté programme were:

- 84% for the benefit of employees in health;
- 64% for public health issues;
- 60% free trial;
- 32% brand image of the company;
- 16% expected a decrease in absenteeism.



92% had not experienced any problems in the implementation of the VigiSanté programme. And 96% were found to comply with the deployment promise, including compliance:

- quality of collaboration with stakeholders of the company (80%);
- provision of health professionals (76%);
- "turnkey" project (72%);
- confidentiality (68%);
- and compliance with the screening schedule (60%).

The overall quality was perceived as very satisfactory for 40% of companies, satisfactory for 56% and unsatisfactory in 4% of cases. In addition, 60% of companies were satisfied to very satisfied with the programme, and would be willing to recommend VigiSanté. Only three companies were willing to finance the establishment of a service such as VigiSanté.

Finally, participation in the screening phase of hypertension in the implementation of the VigiSanté program was 28.5%. On average, 16% of employees present in the sample firms were diagnosed hypertensive. Finally, 95% of companies had employees who were screened with hypertension.

## 4.4 Effects of explanatory variables

### 4.4.1 Patients' point of view

To determine if some expected benefits of the VigiSanté programme were associated with profiles of differentiated patients, we use the logistic regression to assess the impact of each variable on the probability of being motivated by the VigiSanté programme and the probability of improving his/her health status.

#### Being motivated through the use of VigiSanté programme

Factors positively influencing the probability of patients being motivated by the VigiSanté programme were:

- having a simplified navigation on the VigiSanté portal;
- having a medical device to facilitate the measurement of blood pressure;
- feeling of improving health.

**Table 3: Factors influencing the probability of being motivated to use the program VigiSanté**

Variable	Significance
Navigation on the portal	+
Finding information on the portal	Ns
Listening and availability of nurses	Ns
Facilitating blood pressure	+
Having a preference for remote care	Ns
Perception of improving his health	++

<b>Variable</b>	<b>Significance</b>
Gender	Ns
Age	Ns

Notes for Tables 3, 4 and 5: the significance indicates that the variable in question plays a role in the probability of giving an expected benefit. The number of signs "+" or "-" indicates the degree of significance, a large number of signs indicates that the variable has an influence on the importance given to the benefit. A "+" sign indicates that the variable has a positive influence, a "-" negative influence. "Ns" means "not significant", that is to say that the variable is statistically irrelevant in the regression.

However, there was no difference by age or sex of the patients. Similarly, listening and availability of the nurses is not a differentiating factor between patients.

### **Perception of improved health by the VigiSanté programme**

Factors positively influencing the probability of perception of improved health status were:

- being a man aged 46 to 55 years old;
- searching information on one or two specific types of medical information (lifestyle, medication, etc.);
- making an Internet search more than once a year.

**Table 4: Factors influencing the probability of perception of improved health status by the VigiSanté programme**

<b>Variable</b>	<b>Significance</b>
Sex (man)	+++
Age (46-55)	+++
Opinion on VigiSanté	Ns
Discussion with family doctor	Ns
Types of information taken from Internet	++
Frequency of Internet searches	++
Number of consultations with the family doctor	Ns

We found that these people wanted to manage their disease better by becoming a leading actor of his/her health.

#### **4.4.2 Doctors' point of view**

We used the logistic regression to identify factors influencing the probability of observing changes in patient behaviour after the VigiSanté programme, according to doctors.

**Table 5: Factors influencing the probability of observing a change in patient behaviour following the Vigisanté programme**

Variable	Significance
Medical software	Ns
Evocation of its participation	Ns
Facilitating health access	+
Perceived benefits	Ns
Age	Ns

According to GPs, behaviour change seen in their patients was due to the ease of access to healthcare through the Vigisanté programme.

## 4.5 Discussion of findings

The main obstacles for the implementation of the VigiSanté programme were technical. The main difficulty shared by both patients and GPs was the use of the dedicated portal.

Only 20% of GPs involved in the programme used the portal. Almost all of the respondents found it too complicated in terms of information retrieval and navigation. We can see similar trends for patients. 54% of respondents considered that support to the user would allow better use of the portal. In addition, over 40% of respondents had difficulties in finding information on the VigiSanté portal. As a result, use of the portal required a significant cognitive effort for about the half the people who responded to the questionnaires. As the information system is a key success factor in the compliance to such an eHealth service, significant efforts will be made to ensure its ease of use.

However, the implementation of the VigiSanté service met the expectations of patients and health professionals.

From the patients' point of view, medical information present in eHealth programmes can improve diagnosis and treatment. 59% of patients involved in the project experienced an improvement in their health, 80% were satisfied with the follow-up of their hypertension monitoring and support, and more than 80% of attendees would recommend it to relatives.

From the physicians' point of view, the implementation of such a service strengthens the role of the GP. The study shows that for about 69% of GPs, the integration of patients into VigiSanté allowed global health benefits, including on blood pressure.

The cutting edge of the study is the empowerment given by the Vigisanté project, that is to say giving patients the means to become responsible for his/her own health.

We also find that more than half of patients will take information from the Internet to improve their lifestyle, and then learn about a specific disease. In addition, the issue of dematerialised care, that is often regarded as an obstacle to the implementation

of telehealth projects, was not evident in this study, because 84% of patients enjoyed the remote monitoring and the availability of the nurses.

## 5. Domain 5: Economic aspects

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### 5.1 Viewpoint

The viewpoint of the economic analysis is that of the national health insurance.

### 5.2 Selection of economic analysis

For the cost-effectiveness study, an Incremental Cost-Effectiveness Ratio (ICER) is calculated.

To calculate the effectiveness, we use the survival data analysis method. The list of costs is:

- Investment, exploitation, uses.
- Consumption of care data: treatments, hospitalisation, visits to emergency department, medication.

### 5.3 Patient population

We used the data of the VigiSanté patients collected by the information system and the data collected by the National Health Insurance.

### 5.4 Comparators

We used the National Health Insurance data and two comparator groups for the economic analysis.

The data of the first group were made by collecting the consumption of care data of a representative sample of hypertensive patients in terms of age, sex and severity (n=200,000).

The data of the second group were made by collecting consumption of care data of VigiSanté patients one year before (n=317).

### 5.5 Range of costs and measurement,

This section will be completed in the Final Trial evaluation

**Table 6: Types of resources included in the estimation of costs**

Type of costs	Method of data collection	Estimation at patient or group level
Investment in the telemedicine application		

- Physical change of buildings	Interview with staff	Group level
- Technical infrastructure	Interview with staff	Group level
- Education of the staff	Interview with staff	Group level
Running costs:		
- Time used by staff on education of patients	Questionnaire to staff	Patient level
- Time used by staff at the call centre	Questionnaire to staff	Patient level
- Number of tele-consultations	Questionnaire to staff	Patient level
- Rent of telemedicine device	Questionnaire to staff	Patient level
- Staff time used by home care nurse	Questionnaire to staff	Patient level
- Time used by patients	Questions to patient	Patient level
- Time used by relatives	Questions to patient	Patient level
Effects on patients use of health care:		
- Number of readmissions	Register data	Patient level
- Number of inpatient days	Register data	Patient level
- Length of stay for each readmission	Register data	Patient level
- Number of contacts to GP	Register data	Patient level
- Number of contacts to emergency doctor	Register data	Patient level

## 5.6 Prices

This section will be completed in the Final Trial evaluation

**Table 7: Prices used in the calculation of costs (€, 2011-prices)**

Type of costs	Price per unit
Investment and running costs:	
- Physical change of buildings	€€ in total
- Technical infrastructure	€€ in total
- Time used by staff:	
- Nurses	€€ per hour
- Medical doctors	€€ per hour
- Secretary	€€ per hour
- Staff time used by home care nurse	€€ per hour
- Rent of telemedicine device	€€ per Briefcase
- Time used by patients	€€ per hour
- Time used by relatives	€€ per hour
- Transport	€€ per kilometre
Effects on patients use of health care:	

Type of costs	Price per unit
- Readmissions	€€ per readmission
- Inpatient days	€€ per day
- Outpatient visits	€€ per visit
- GP visits	€€ per visit
- Emergency department visits	€€ per visit

## 5.7 Average use of resources

This section will be completed in the Final Trial evaluation

**Table 8: Average use of resources per patient in the Intervention and Control Groups**

Type of costs	Mean use per patient in			
	Intervention Group		Control Group	
Running costs of the telemedicine service and comparator:				
- Time used by staff on education of patients	## min.	ci: ##-##		
- Time used by staff at the call centre	## min.	ci: ##-##		
- Number of tele-consultations	#	ci: ##-##		
- Number of inpatient days	# days	ci: ##-##	# days	ci: ##-##
.....				
- Time used by patients	## min	ci: ##-##	## min.	ci: ##-##
- Time used by relatives	## min	ci: ##-##	## min.	ci: ##-##
-				
Effects on patients' use of health care:				
- Number of readmissions	## readmis.	ci: ##-##	## readmis.	ci: ##-##
- Length of stay for each readmission	## days	ci: ##-##	## days	ci: ##-##
- Staff time used by home care nurse	### min.	ci: ##-##	### min.	ci: ##-##
- Number of contacts to GP	## contacts	ci: ##-##	## contacts	ci: ##-##
- Number of contacts to emergency doctor	## contacts	ci: ##-##	## contacts	ci: ##-##

## 5.8 Measured effects and benefits

This section will be completed in the Final Trial evaluation

## 5.9 Average costs

This section will be completed in the Final Trial evaluation

**Table 9: Average costs of the treatment per patient in the intervention and control group (€, 2011-prices)**

Type of costs	Mean cost per patient in Intervention Group	Confidence interval	Mean cost per patient in Control Group	Confidence interval
Investment in the telemedicine application				
- Physical change of buildings	€#####			
- Technical infrastructure	€#####			
- Education of the staff	€#####			
Total investment costs	€#####	ci: ##-##		
Running costs:				
- Staff	€#####	ci: ##-##	€#####	ci: ##-##
- Telemedicine devices	€#####	ci: ##-##		
- Inpatient days	€#####	ci: ##-##	€#####	ci: ##-##
- Readmissions	€#####	ci: ##-##	€#####	ci: ##-##
- Emergency department visits	€#####	ci: ##-##	€#####	ci: ##-##
- Home care nurse	€#####	ci: ##-##	€#####	ci: ##-##
- GP visits	€#####	ci: ##-##	€#####	ci: ##-##
- Transport	€#####	ci: ##-##	€#####	ci: ##-##
Total running costs €	€#####	ci: ##-##	€#####	ci: ##-##
Time costs (lost productivity):				
- Time used by patients	€#####	ci: ##-##	€#####	ci: ##-##
- Time used by relatives	€#####	ci: ##-##	€#####	ci: ##-##
Total time costs	€#####	ci: ##-##	€#####	ci: ##-##
<b>Total costs</b>	<b>€#####</b>	<b>ci: ##-##</b>	<b>€#####</b>	<b>ci: ##-##</b>

### 5.10 Incremental cost-effectiveness

This section will be completed in the Final Trial evaluation

The Incremental Cost-Effectiveness Ratio (ICER) is calculated as follows.

$$ICER = \frac{Blood\ pressure_{Vigisanté} - Blood\ pressure_{WithoutVigisanté}}{Costs_{Vigisanté} - Costs_{WhitoutVigsanté}}$$



**Table 10: Incremental cost-effectiveness ratios (ICER) in €, 2011-prices**

Case	Number of patients	Mean ICER	Confidence interval
Base case	XXX	€#####	ci: ## - ##
Men	XXX	€#####	ci: ## - ##
Women	XXX	€#####	ci: ## - ##
Patients aged > 70	XXX	€#####	ci: ## - ##
Patients aged < 71	XXX	€#####	ci: ## - ##

### 5.11 Sensitivity analysis

This section will be completed in the Final Trial evaluation

### 5.12 Results from the business case

This section will be completed in the Final Trial evaluation

**Table 11: Estimated expenditures and revenue for hospital x of implementation of telemedicine for xxx patients (€, 2011-prices)**

Type of costs	Total expenditures or revenue
Expenditures:	
- Education of the staff	€ #####
- Physical change of offices	€ #####
- Telemedicine devices	€ #####
- Inpatient days	€ #####
- Readmissions	€ #####
- Outpatient visits	€ #####
<b>Total expenditures</b>	<b>€ #####</b>
Reimbursement	
- DRG value of inpatient activity	€ #####
- DRG-value of inpatient activity	€ #####
<b>Total reimbursement</b>	<b>€ #####</b>

### 5.13 Discussion of findings

This section will be completed in the Final Trial evaluation

## 6. Transferability assessment

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### 6.1 Transferability of clinical effects

This section will be completed in the Final Trial evaluation

**Table 12: Domain 2-3: Safety and clinical outcomes**

<b>Scalability</b>	<i>Compare demographic characteristics with national data</i>	<i>Determine differences and assess how that would influence results on a national basis</i>
<b>Generalisability</b>	<i>Widening of inclusion criteria</i>	<i>Assess if other types of patients (i.e. lower or higher severity of disease) will gain more or less compared to trial patients</i>

### 6.2 Transferability of economic effects

This section will be completed in the Final Trial evaluation

**Table 13: Domain 5: economic outcomes**

<b>Scalability</b>	<i>Assess what would be necessary if intervention should be scaled up within the country. How many telemedicine centres, how many patients etc.</i>	<i>Calculate the consequences in terms of costs/patient</i>
<b>Generalisability</b>	<i>Assess what would happen if inclusion criteria were widened. How many patients would benefit, how many centres would be necessary etc.</i>	<i>Calculate the consequences in terms of cost/patient and QALYs</i>

### 6.3 Transferability of organisational effects

This section will be completed in the Final Trial evaluation

**Table 14: Domain 6: Organisational aspects**

<b>Scalability</b>	<i>Assess whether organisational aspects are unique for pilot within country</i>	<i>Describe how it is unique and what would be necessary for other regions if they decided to implement the telemedicine solution</i>
<b>Generalisability</b>	<i>Assess if organisational changes is necessary for broadening inclusion criteria</i>	<i>Discuss what would be necessary for the organisation, if inclusion criteria were broadened – and thus more patients included</i>