



**IMCA II**

# **HES Feasibility Study**

**Protocol**

**(Versión 1.0)**

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# **1. HES Feasibility Study Protocol**

## **1.1. Research Study Protocol**

### **1.1.1. Background**

Most countries of the European Union have carried out Health Interview Surveys (HIS) in order to assess the health status of the population and develop strategies for health and health care policy decision making. The first health interview survey was carried out in USA in 1957 and progressively Finland (1964), Australia (1977), Italy (1980) implemented their own surveys<sup>1</sup>. During the last two decades many other countries have performed a national survey.

Although Health Interview Surveys (HIS) have been considered very useful to monitor health status of the population increasingly it has been recognized that they have some important limitations. Among these limitations, perhaps the most important one, is that for certain chronic conditions, in order to measure prevalence and severity of the disease the performance of measurements is absolutely necessary<sup>2</sup>. Due to this situation, several countries have started to implement Health Interview & Examination Surveys (HES) in order to overcome part of the problems mentioned. However, only 10 European countries (Germany, Cyprus, Croatia, Finland, Slovakia, Holland, Ireland, Norway, Poland and United Kingdom)<sup>3,4</sup>. Among these countries only few countries perform these surveys periodically. The Scottish Health Survey is performed every 3-4 years<sup>5</sup>, the Finnish and German National Health Examination Survey is performed every 5-7 years<sup>6</sup>. Only in United Kingdom the Health Survey for England is performed every year<sup>7</sup>.

The reasons that could explain why in many countries HES have not been implemented yet could be the high complexity of organizing the field work, the high cost and the acceptability of measurements in different cultures. From the examination of 11 surveys it is possible to see a wide range of non response rates (3 to 75%)<sup>1</sup>. In order to harmonize and to overcome part of the general problems of the organization and management of HES in Europe, DG SANCO is promoting the development of a European Health Survey System (EHSS)<sup>8</sup> which would include the development of HES at national level. As a first step is promoting the development of studies that could recommend "Modules" to include in future HES for specific diseases including questionnaires, methods of management and organizing the fieldwork and outcomes to obtain.

In the field of respiratory diseases, the information collected at European level by HES is very limited and most of the information available come from large international studies such as the European Community Respiratory Health Survey (ECRHS)<sup>9</sup> and the International Study of Asthma and Allergies in Childhood (ISAAC)<sup>10</sup>. The importance of health examination for respiratory diseases is best illustrated by the case of COPD for which an acceptable case definition should be based on the spirometry (GOLD 2007). Because

spirometry is a complex measure prevalence that is usually performed in specialized centres internationally comparable prevalence figures for COPD have not been available until very recently (Menezes Lancet 2006, Buist Lancet 2007). An important step forward for these studies has been the availability of portable spirometers which have largely facilitated field work.

Based on the experience of these large studies we propose to develop a pilot study in order to assess the feasibility and effectiveness of using the Motohealth system as a tool for the administration of at-home measurements including spirometry in large scale surveys at national and international level and to evaluate to what extent this system can improve the acceptability of measurements and response rates. The results of this study would help to make recommendations for a module on respiratory diseases to be incorporated in future HES.

### **1.1.2. Objectives**

The main objectives of the study are:

- 1) To assess the feasibility of using the Motohealth system as a tool for performing interviews and measurements at home in the context of large scale respiratory surveys at national and international level.
- 2) To evaluate to what extent the Motohealth system can improve response rates to questionnaires, the acceptability of measurements performance and biological samples collection when the measurements are performed at home in comparison to other settings such as a primary health care centre.

### **1.1.3. Material and methods**

#### **1.1.3.1. Study Design and Population**

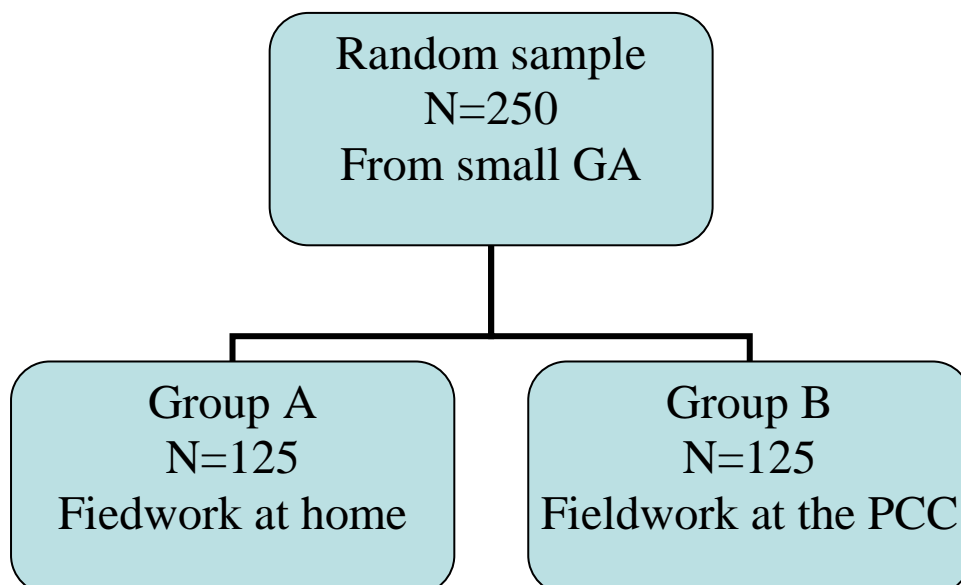
In the context of this HES feasibility study participant partners will have the opportunity to select among two different study designs: 1) A randomized control trial which we will call Model A and 2) a cross sectional design which we will call Model B.

### **1.1.3.1.1. Model A**

A total of 250 individuals aged from 6 to any age will be randomly selected from a population register of a defined geographical area. This geographical area can be a district, a catchment area of a health care centre or other alternative well defined geographical area. Individuals selected will be randomly selected by age group and sex and allocated in two groups: a) individuals to whom interview and measurements will be performed at home and b) individuals to whom interview and measurements will be performed in a primary health care centre. All participants, according to their group, will be informed by post to explain the main characteristics of the study, the characteristics of the questionnaire and measurements to be performed. For both groups questionnaire and measurements will be the same. Once they have received this information a fieldworker will contact them by telephone in order to confirm their participation in the study or rejection and will try to perform a brief questionnaire in order to get basic information from individuals that refused to participate.

Once they have accepted to participate, the study coordinator will inform them about the date in which interview and measurements will be performed. During this date, previously to performing any measurement, the fieldworker will give to individuals more information on the measurements and they will be asked to sign a consent form. Individuals will have the opportunity to give consent for all measurements or only some of them.

#### **Study design scheme**



### **1.1.3.1.2. Model B**

A total of 150 individuals aged from 6 to any age will be randomly selected from a population register of a defined geographical area. Alternatively, the selection of households may also be considered. This geographical area can be a district, a catchment area of a health care centre or other alternative well defined geographical area. Individuals or households will be randomly selected from the general population. All participants, will be informed by post about the main characteristics of the study, the questionnaire and measurements to be performed. Once they have received this information a fieldworker will contact them by telephone in order to confirm their participation in the study or rejection and will try to perform a brief questionnaire in order to get basic information from individuals refusing to participate.

Once they have accepted to participate, the study coordinator will inform them about the date in which interview and measurements will be performed. During this date, previously to performing any measurement, the fieldworker will give to individuals more information on the measurements and they will be asked to sign a consent form. Individuals will have the opportunity to give consent for all measurements or only some of them.

### **1.1.3.1.3. Which Model will perform each country?**

In principle the first feasibility study will be conducted in Spain using the Model A. Other four partners will perform the HES feasibility study: Sweden, Germany and Italy (Pisa and Rome) and although ideally would be good to perform the same model, due the characteristics of each country partners will be able to choose between Model A and Model B. In addition to these countries other countries may choose to perform the study providing that the sample size is limited and technology will be provided by the coordinating centre. Countries that already could considerer to perform the study without national funding are France, Poland, Norway and Finland.

### **1.1.3.2. Technology and communications system: Motohealth**

The Motohealth system is a tool that has been developed to facilitate the management of large (national-international) epidemiological studies integrating the tasks of questionnaire design, measurements carried out by sensors, management of fieldwork and monitoring data collection and transmission on-line. The system basically allows to perform

measurements at home (spirometry, blood pressure, weight, etc), collect data on specific questionnaires and transmit data via web to a central server. A fieldworker visits the individuals or patients and at home perform the measurements, using a Portable PC and data are transmitted to the PC via Bluetooth and from the PC to the central server. The system allows to transmit data from everywhere with a telephone connection and web access. The system allows to perform complex measurements at home in the context of epidemiological studies and avoids the need to invite patients to the hospital or a health care centre.

The three collaborating centres of Barcelona (CLINIC-PAMEM-IMIM) have designed a new Motohealth platform which is operated through the web. This platform allows the questionnaires design and integrates the tasks of questionnaire data collection, perform the measurements at home carried out by sensors, management of fieldwork and monitoring data collection and transmission on-line to the central server.

The present application will be hosted at Hospital Clinic of Barcelona and will be accessible at (<https://linkcare.clinin.ub.es/mhworld>). The system has what we call a MHWorld Backend Application supported by a central server from where the system is organized and monitored. In the system four main roles have been defined. First, the system administrator who from the MHWorld Backend Application controls the system giving access and passwords to all professionals required according to their roles to be performed and accessibility needs. The second, the study manager who is responsible for creating and administering studies, designing questionnaires, describing activities, import/export participants to the study, monitor data collection and export data to central server. Third, the phone operator who is the first persons that establishes the first contact with all participants, interview participants with a brief questionnaire and according to study protocol makes an appointment for interview and measurements performance (either at home or in a health care centre). Fourth, the field worker who is responsible for interviewing participants and performing measurements.

All field workers will be provided with a Portable PC with a telephone card for communication with MHWorld Backend Application. Interviews will be performed either at home or in a health care centre, data will be introduced directly to the PC by the fieldworker and data transmitted to the central server. Measurements will also be performed by the fieldworker using sensors for different measurements. Once the measurement is done, via bluetooth will be transmitted to the PC and from the PC to the central server.

### **1.1.3.3. Data, measurement and biological samples collection**

**Interview/questionnaires: children and adults:** During the first contact established by the "phone operator" a brief questionnaire on personal characteristics and respiratory symptoms will be administered to all individuals selected for an initial contact. All individuals accepting to participate will be face-to-face interviewed using the same structured questionnaires, administered by trained interviewers. For participants aged from 6 to 11 parents will be interviewed using the children's questionnaire based on a selection of questions from the ISAAC II protocol. For children from 11 to 14 questionnaire will be completed from children answers. The questionnaire will include information on socio-demographics, respiratory symptoms (wheeze, breathlessness, rhinitis, eczema), asthma management & treatment, smoking habits of parents and other home exposures. Participants aged 14+ to any age will be interviewed using the adults questionnaire based on a selection of questions from the ECRHS II questionnaire. The questionnaire include information on socio-demographics, respiratory symptoms (wheeze, breathlessness, rhinitis, eczema), asthma management & treatment, smoking habits and other home or environmental exposures.

**Measurements to be performed and sensors characteristics:** For each study participant, the following measurements will be performed: spirometry, blood pressure, pulse-oximetry, weight and height. All these measurements with the exception of height will be performed using instruments called "sensors" that have the capacity to transmit the data directly to a PC via bluetooth.

The spirometer to be used will be the NDD EasyOne Model 2001 that meets published recommendations of the European Respiratory Society (ERS) and the American Thoracic Society (ATS), the National Lung Health Education Program (NLHEP). Blood pressure will be measured using a Blood Pressure Monitor UA-767BT from A&D Medical. The pulse-oximetry will be measured using a NONIN 4000 Avant Bluetooth sensor. The weight will be measured by the sensor from A&D Medical UC-321PL. The capacity, speed, timing of data transmission and data quality of the central database will be used as main indicators to assess objective one.

**Blood sample collection:** A blood sample will be collected from each subject in EDTA/blank (without anticoagulant) tubes by a nurse in Spain and by a physician in those countries where from the legal point of view is required. The blood will be processed immediately after extraction (or at least in the same day) after extraction, centrifuged, and

stored at  $-80^{\circ}\text{C}$ . The following tests will be performed for each sample: Hemogram, Cholesterol, C-Reactive Protein, Creatinine and two allergens (Dermatophagoides pteronissius and cat).

### **1.1.3.4. Data management**

A database including all personal details from each participant selected will be created. This database will meet the characteristics of the Motohealth system regarding the number of fields to include and the details of each variable. Based on this information, all participants will have a unique code assigned when they enter into the study. In addition, a geographical area code will also be assigned to all participants. This code will be assigned based on the participant's address and to be used for individual selection during fieldwork management. Each country will use this code according to their own specific situation and needs. Biological samples will be coded at the moment of collection. The laboratory will create a register for all samples received including data on participant code, time of delivery and date.

In all countries participating, the face-to-face questionnaire will be administered by an interviewer with a tablet PC or portable PC connected with a USB modem (3G) with the central MHWorld Backend Application and data will be transferred immediately after completion to the central server, where separate files will be kept for the coded database and the personal information database. The telecommunication from all countries with the central server will have to be tested and costs of "roaming" studied. Data will be stored in the central server in an Excel format and will capture the data from the designed questionnaires automatically.

### **1.1.3.5. Statistical analysis**

A descriptive analysis of all variables included in the study will be performed. Comparisons between categorical variables will be performed using Chi<sup>2</sup> test. Logistic regression will be used to analyze the relationship between outcomes and independent variables taking into account potential confounders and heterogeneity between regions. Analysis will be mainly performed with STATA 8.1.

In the case of Model A, assuming an alpha risk of 0,05 and  $\beta$  of 0,20 with a response rate in the group A of 85%, in order to detect a difference of 20% between group A and B a

sample size of 119 in each group would be required. In countries or centres performing the same design pooled and by-centre analysis will be performed.

#### **1.1.4. Ethical Issues And Safety Of The Participants**

**Ethical approval and informed consent:** The studies will be submitted to approval by the local ethics committees. During the study, national and international directives will be followed (deontological code, Helsinki declaration). A signed informed consent to participate will be obtained from all study subjects prior interview or measurements.

**Confidentiality:** Personal data will be available from MHWorld Backend Application only to authorized persons to contact participants. All participants will have an identification code assigned when they accept to participate. Database containing data from interviews and biological samples will contain only the code of the subject. In Spain, the rules of confidentiality and data protection established by the Act 15/1999.

**Safety:** All measurements will be performed taking into account all safety issues. Some measurements such as blood sample extraction may cause some nuisance or a small haematoma which may be specially important in children. To reduce them an anaesthetic cream will be used for venopuncture. Nurses will be trained for the patient's safety. All participating centres must comply with the current law and the study have to be approved by the corresponding Ethical Committee.

#### **1.1.5. Timing And Fieldwork Training**

The first feasibility study will be performed in Barcelona and will be carried out during the last week of November and December. In case it is necessary it will be continued during the first part of January 2008. It is planned that the rest of countries performing the study will be able to carry it out from March to May 2008. Training sessions for field work coordinators in participating countries will be planned during the days before the general meeting in February. All countries performing the study will need to send a fieldwork coordinator to Barcelona for training. This person should already be trained in performing spirometries and able to perform blood extractions.

## 1.1.6. References

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## **1.2. Questionnaires**

### **1.2.1. Spanish questionnaires**

### 1.2.1.1. Spanish Adults Questionnaire

## IMCA II

### HES Feasibility Study

(GA<sup>2</sup>LEN screening questionnaire)

#### Adult's questionnaire- Spanish Version

PARA CONTESTAR LAS PREGUNTAS MARCAR LA CASILLA APROPIADA  
SI NO ESTÁ SEGURO DE LA RESPUESTA MARQUE 'NO'

- |   |   |                                |
|---|---|--------------------------------|
| 1. ¿Ha tenido sibilancias o pitos en el pecho alguna vez <b>en los últimos 12 meses?</b><br><i>SI 'NO' PASAR A LA PREGUNTA 2. SI 'SÍ' PASAR A LA PREGUNTA 1.1</i> | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 1.1 ¿Ha tenido falta de aire cuando estaban presentes los silbidos o pitos?   | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 1.2 ¿Ha tenido estos silbidos o pitos cuando <b>no</b> estaba resfriado?  | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 2. ¿Se ha despertado con una sensación de opresión o tirantez en el pecho alguna vez <b>en los últimos 12 meses?</b>  | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 3. ¿Se ha despertado por la noche a causa de un ataque de falta de aire alguna vez <b>en los últimos 12 meses?</b>  | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 4. ¿Se ha despertado por un ataque de tos alguna vez <b>en los últimos 12 meses?</b>  | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 5. ¿Arranca o saca esputos la mayoría de los días al menos tres meses cada año?   | NO<br><input type="checkbox"/>  | SI<br><input type="checkbox"/> |
| 6. ¿Tiene o ha tenido <b>alguna vez</b> asma?<br><i>SI 'NO' PASAR A LA PREGUNTA 7. SI 'SÍ' PASAR A LA PREGUNTA 6.1</i>  | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 6.1 ¿Que edad tenía cuando tuvo el primer ataque de asma?<br>(Si no está seguro, indique lo que crea más apropiado)   | AÑOS<br><input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> |                                |
| 6.2 ¿Ha sido hospitalizado <b>alguna vez</b> por el asma?   | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 6.3 ¿Ha tenido algún ataque de asma <b>en los 12 últimos meses?</b>   | NO<br><input type="checkbox"/>  | SI<br><input type="checkbox"/> |
| 6.4 ¿Toma <b>actualmente</b> alguna medicación (incluyendo inhaladores, aerosoles o pastillas) para el <b>asma?</b>   | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
| 7. ¿Tiene usted alguna alergia nasal, incluyendo rinitis?<br><i>SI 'NO' PASAR A LA PREGUNTA 8. SI 'SÍ' PASAR A LA PREGUNTA 7.1</i>                                | NO<br><input type="checkbox"/>  | SÍ<br><input type="checkbox"/> |
|   | NO  | SÍ                             |

7.1 ¿Ha tenido problemas de alergias nasales en los últimos 12 meses?

NO SÍ

7.2 ¿Ha tenido problemas por alergias nasales durante más de 4 días en una semana?

NO SÍ

7.3 Si la respuesta es 'SÍ', ¿ha durado más de 4 semanas seguidas?

NO SÍ

8. ¿Ha tenido la nariz tapada durante más de 12 semanas en los últimos 12 meses?

NO SÍ

9. ¿Ha tenido dolor o presión alrededor de la frente, nariz u ojos durante más de 12 semanas en los últimos 12 meses ?

NO SÍ

10. ¿Ha tenido mucosidad anormal en la nariz o la garganta durante más de 12 semanas en los últimos 12 meses?

NO SÍ

11. ¿Ha perdido olfato total o parcialmente durante más de 12 semanas en los últimos 12 meses?

NO SÍ

12. ¿Le ha dicho un medico que tiene sinusitis crónica?

NO SÍ

13. ¿Alguna vez ha tenido algún sarpullido o erupción cutánea con picor que apareciera y desapareciera durante al menos 6 meses?

**SI 'NO' PASAR A LA PREGUNTA 14. SI 'SÍ' PASAR A LA PREGUNTA 13.1'**

13.1 ¿Ha tenido esta erupción con picor en los últimos 12 meses?

NO SÍ

13.2 ¿Le ha afectado solo a las manos?

NO SÍ

14. ¿Ha tenido alguna vez eczema u otro tipo de alergia en la piel?

15. ¿Ha tenido algún problema respiratorio en las siguientes 3 horas de haberse tomado un analgésico?

**SI 'NO' PASAR A LA PREGUNTA 16. SI 'SÍ' PASAR A LA PREGUNTA 15.1'**

15.1 Por favor escriba el nombre del medicamento .....

NO SÍ

16. ¿Fuma o ha fumado durante más de un año?

**['SÍ' significa: al menos un cigarrillo al día o un puro a la semana durante un año]**

**SI 'NO' PASAR A LA PREGUNTA 17. SI 'SÍ' PASAR A LA PREGUNTA 16.1**

16.1 ¿A qué edad empezó a fumar?   AÑOS

NO SÍ

16.2 ¿Ha fumado durante el último mes?

**SI 'SI' PASAR A LA PREGUNTA 16.3. SI 'NO' PASAR A LA PREGUNTA 16.2.1**

AÑOS

16.2.1 ¿Qué edad tenía cuando dejó de fumar?

--	--

16.3 **De promedio**, ¿cuánto ha fumado?

Cigarros por día

--	--

*Marque solo una casilla!*

17. En estos momentos usted está::

- a. trabajando por cuenta ajena
- b. trabajando por cuenta propia
- c. en paro
- d. no está trabajando por motivos de salud
- e. encargado de tareas domesticas a tiempo completo
- f. estudiante a tiempo completo
- g. jubilado
- h. otros

	1.
	2.
	3.
	4.
	5.
	6.
	7.
	8.

18. Está trabajando en la actualidad:

- a. ¿Como trabajador sanitario (ej..enfermera, auxiliar médico, doctor ...)?
- b. ¿En un trabajo involucrado con cualquier tipo de limpieza?

NO	SÍ

19. ¿Cuál es su fecha de nacimiento?

DÍA	MES	AÑO

20. ¿Qué día es hoy?

DÍA	MES	AÑO

21. ¿Es hombre o mujer?

H	M

¿Podemos volver a contactar con usted para pedirle más información y ayudarnos más en esta investigación?

NO	SÍ

**GRACIAS POR SU AYUDA!**

## 1.2.1.2. Spanish Children Questionnaire

### IMCA II HES Feasibility Study (Questions selected from the ISAAC II protocol) Children's questionnaire – Spanish Version

1. ¿Su hijo es un niño o una niña?  Niño  Niña
2. ¿Cual es la fecha de nacimiento de su hijo/a? \_\_\_/\_\_\_/\_\_\_  
—
3. ¿Su hijo/a nació en España?  Si  No
4. ¿En caso negativo, en que país nació? \_\_\_\_\_
5. ¿**En el pasado**, su hijo/a ha tenido alguna vez sibilancias o “pitos” en el pecho?  Si  No  
*SI HA CONTESTADO QUE “NO” SALTE A LA PREGUNTA 10*
6. ¿**En los últimos doce meses**, su hijo/a ha tenido sibilancias o “pitos” en el pecho?  Si  No  
*SI HA CONTESTADO QUE “NO” SALTE A LA PREGUNTA 10*
7. ¿**En los últimos doce meses**, cuántos ataques de sibilancias o pitos en el pecho ha tenido su hijo/a?  
 Ninguno  4 a 12  
 1 a 3  Más de 12
8. ¿**En los últimos doce meses**, cuántas veces se ha despertado su hijo/a por la noche debido a sibilancias o “pitos”?  
 Nunca se ha despertado por pitos  
 Menos de dos noches por mes  
 Menos de una noche a la semana  
 Una o más noche por semana  
 Cada noche o la mayoría de noches a la semana
9. ¿**En los últimos doce meses**, las sibilancias i “pitos” en el pecho han sido tan importantes como para que su hijo/a haya tenido que parar de respirar cada dos palabras seguidas?  Si  No

10. ¿Su hijo/a ha tenido **alguna vez** asma?  Si  No
11. ¿**En los últimos doce meses**, su hijo/a ha utilizado pastillas, aerosoles u otros fármacos por problemas de sibilancias, “pitos” o asma?  Si  No
12. ¿Tiene alguna guía o plan escrito que indique como prevenir y tratar los problemas de sibilancias o asma de su hijo/a?  Si  No
13. ¿**Alguna vez**, su hijo/a ha tenido estornudos, le ha goteado la nariz o se le ha tapado la nariz **SIN** haber estado resfriado/a o con gripe?  Si  No
14. ¿**En los últimos doce meses**, su hijo/a ha tenido estornudos, le ha goteado la nariz o se le ha tapado la nariz **SIN** haber estado resfriado/a o con gripe?  
**SI HA CONTESTADO QUE “NO” SALTE A LA PREGUNTA 16.**
15. ¿**En los últimos doce meses**, su hijo/a ha tenido estos problemas nasales acompañados de picor y lagrimeo en los ojos?  Si  No
16. ¿**Alguna vez** ha tenido su hijo/a alergia nasal, incluyendo “fiebre del heno” o rinitis?  Si  No
17. ¿**Alguna vez** ha tenido su hijo/a al menos durante 6 meses manchas rojas en la piel que pican y aparecen y desaparecen?  
**SI HA CONTESTADO QUE “NO” SALTE A LA PREGUNTA 20.**
18. ¿**En los últimos doce meses**, su hijo/a ha tenido estas manchas que pican?  Si  No
19. ¿Estas manchas rojas que pican, le han salido alguna vez en alguno de estos lugares:
- En los pliegues de los codos, detrás de la rodilla,  
en el empeine, debajo de las nalgas, alrededor del cuello,  
ojos o orejas?  Si  No
20. ¿**Alguna vez** su hijo/a ha tenido eczema?  Si  No
21. ¿Sabe usted si a su hijo/a **alguna vez** le han realizado pruebas de alergia?  Si  No
22. En caso afirmativo, ¿**Alguna vez** le han resultado positivas?  Si  No
23. ¿**Alguna vez** su hijo/a ha recibido alguna inyección para prevenir o tratar el asma?  Si  No
24. ¿La madre de su hijo/a fuma o fumaba?

	En el presente	Durante el primer año de vida	Durante el embarazo
Si	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

25. ¿En el momento actual, alguien fuma dentro de casa?  Si  No

Si es que si, cuantos cigarrillos se fuman por día en casa?  
Por ejemplo, si la madre se fuma 4 más el padre que se fuma 5 más  
otra persona que se fuma tres, total son 12 cigarrillos)

Menos de 10 cigarrillos   
10 – 20 cigarrillos   
Mas de 20 cigarrillos

26. ¿La madre , ha tenido alguna de estas enfermedades?

Asma   
Fiebre del Heno   
Eczema

27. ¿El padre, ha tenido alguna de estas enfermedades?

Asma   
Fiebre del Heno   
Eczema

28. ¿En qué país nació la madre de su hijo/a?

\_\_\_\_\_

29. ¿En qué país nació el padre de su hijo/a?

\_\_\_\_\_

30. ¿Cual es el nivel de estudios más alto completado por el padre y la madre del niño/a?

	Padre	Madre
No sabe leer ni escribir	<input type="checkbox"/>	<input type="checkbox"/>
No ha cursado estudios pero sabe leer y escribir	<input type="checkbox"/>	<input type="checkbox"/>
Estudios primarios incompletos	<input type="checkbox"/>	<input type="checkbox"/>
EGB o similar	<input type="checkbox"/>	<input type="checkbox"/>
FP o similar	<input type="checkbox"/>	<input type="checkbox"/>
Bachillerato / BUP o similar	<input type="checkbox"/>	<input type="checkbox"/>
COU o similar	<input type="checkbox"/>	<input type="checkbox"/>
Estudios universitarios de grado medio	<input type="checkbox"/>	<input type="checkbox"/>
Estudios universitarios superiores	<input type="checkbox"/>	<input type="checkbox"/>
Educación especial	<input type="checkbox"/>	<input type="checkbox"/>
Prefiere no contestar	<input type="checkbox"/>	<input type="checkbox"/>

31. ¿Quien ha contestado el cuestionario?  
persona  Padre  Madre  Otra

32. ¿Cuando se ha contestado el cuestionario?

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Día Mes Año

## **1.2.2. Italian Questionnaires**

## 1.2.2.1. Italian Adults Questionnaire

### IMCAII Studio di fattibilità della HES Questionario per gli adulti

Codice area  
Codice personale  
Campione


PER RISPONDERE ALLE DOMANDE PER FAVORE BARRI LA CASELLA APPROPRIATA



SE NON E' SICURO DELLA RISPOSTA PER FAVORE SCELGA 'NO'

NO	SI
<input type="checkbox"/>	<input checked="" type="checkbox"/>

1. Ha avuto sibili o fischi al torace almeno una volta negli ultimi 12 mesi?

SE 'NO' VADA ALLA DOMANDA 2 SE 'SI' VADA ALLA DOMANDA 1.1



NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

1.1 Si è mai sentito del tutto senza fiato quando il sibilo era presente?

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

1.2 Ha mai avuto sibili o fischi quando non aveva il raffreddore?

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

2. Si è mai svegliato con un senso di oppressione al petto negli ultimi 12 mesi?

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

3. E' mai stato svegliato da un attacco di difficoltà di respiro almeno una volta negli ultimi 12 mesi?



NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

4. E' mai stato svegliato da un attacco di tosse almeno una volta negli ultimi 12 mesi?

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

5. Ha mai espettorato (catarro) la maggior parte dei giorni per almeno tre mesi all'anno?

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

NO SI

6. Ha **mai** avuto l'asma?

**SE 'NO' VADA ALLA DOMANDA 7**

**SE 'SI' VADA ALLA DOMANDA 6.1**



6.1 A che età ha avuto il suo primo attacco d'asma?  
(Se insicuro, riporti la stima migliore!)

ANNI

6.2 E' **mai** stato ricoverato in ospedale per un attacco d'asma?

NO SI

6.3 Ha avuto un attacco d'asma **negli ultimi 12 mesi?**

NO SI



6.4 **Attualmente** sta prendendo una qualsiasi medicina (inalatori, aerosol o pasticche) per l'**asma?**

NO SI

7. Ha qualche allergia nasale, compreso raffreddore da fieno?

**SE 'NO' VADA ALLA 8**

**SE 'SI' VADA ALLA 7.1**



7.1 Ha avuto problemi per l'allergia nasale **negli ultimi 12 mesi?**

NO SI

7.2 Ha mai avuto problemi per l'allergia nasale per **più di 4 giorni a settimana?**

NO SI

7.3 **Se SI** è successo per **più di 4 settimane di seguito?**

NO SI

8. Ha avuto il naso tappato **per più di 12 settimane negli ultimi 12 mesi?**

NO SI

9. Ha avuto dolore o pressione alla fronte, naso od occhi  
**per più di 12 settimane negli ultimi 12 mesi?**



NO SI

10. Ha avuto emissioni di muco incolore dal naso o catarro incolore in gola  
**per più di 12 settimane negli ultimi 12 mesi?**

NO SI

11. Il suo senso dell'olfatto si è ridotto o è scomparso  
**per più di 12 settimane negli ultimi 12 mesi?**

NO SI



12. Un dottore le ha mai detto che Lei ha una sinusite cronica? NO  SI

13. Ha mai avuto un rossore con prurito che appariva e scompariva per almeno 6 mesi? NO  SI   
**SE 'NO' VADA ALLA DOMANDA 14 SE 'SI' VADA ALLA DOMANDA 13.1**



13.1 Ha avuto questo rossore con prurito negli ultimi 12 mesi? NO  SI

13.2 Riguarda solo le Sue mani?



NO  SI

14. Ha mai avuto eczema o qualsiasi tipo di dermatite allergica? NO  SI

15. Le è mai successo di avere difficoltà a respirare entro tre ore dall'aver preso un analgesico? NO  SI

**SE 'NO' VADA ALLA DOMANDA 16 SE 'SI' VADA ALLA DOMANDA 15.1**



15.1 Per favore scriva il nome del medicinale .....

16. Ha mai fumato per almeno un anno? NO  SI

**['SI' significa almeno una sigaretta al giorno o un sigaro a settimana per un anno]**

**SE 'NO' VADA ALLA DOMANDA 17 SE 'SI' VADA ALLA DOMANDA 16.1**



16.1 Che età aveva quando ha iniziato a fumare? ANNI

16.2 Ha fumato nell'ultimo mese?

NO  SI

**SE 'SI' VADA ALLA DOMANDA 16.3 SE 'NO' VADA ALLA DOMANDA 16.2.1**



16.2.1 Che età aveva quando ha smesso di fumare? ANNI

16.3 In media quanto fuma (o fumava)? Sigarette al giorno

**Segni solo una casella!**

17. Lei attualmente è:

- a. lavoratore dipendente
- b. libero professionista
- c. disoccupato
- d. non lavora perché in malattia
- e. casalinga a tempo pieno
- f. studente a tempo pieno
- g. pensionato
- h. altro

<input type="checkbox"/>	1.
<input type="checkbox"/>	2.
<input type="checkbox"/>	3.
<input type="checkbox"/>	4.
<input type="checkbox"/>	5.
<input type="checkbox"/>	6.
<input type="checkbox"/>	7.
<input type="checkbox"/>	8.

18. Lei attualmente lavora:

- a. Come operatore sanitario (es. come infermiere, tecnico di laboratorio, dottore, paramedico o simili)?

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>



- b. In un'occupazione che prevede prevalentemente pulizie?

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>

19. Qual è la Sua data di nascita?

GIORNO	MESE	ANNO
<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	19 <input type="checkbox"/> <input type="checkbox"/>

20. Qual è la data di oggi?

GIORNO	MESE	ANNO
<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	20 <input type="checkbox"/> <input type="checkbox"/>

21. Lei è maschio o femmina?

M	F
<input type="checkbox"/>	<input type="checkbox"/>



**Possiamo contattarla in futuro così che possa aiutarci ancora in questa ricerca e fornirci ulteriori informazioni?**

NO	SI
<input type="checkbox"/>	<input type="checkbox"/>



9. Negli ultimi 12 mesi, i sibili o fischi sono stati abbastanza gravi da far sì che il bambino potesse dire solo una o due parole tra un respiro e un altro?  Sì  No
10. Il Suo bambino ha mai avuto l'asma?  Sì  No
11. Negli ultimi 12 mesi, il Suo bambino ha assunto una qualsiasi medicina, pillola, aerosol od altri trattamenti per i sibili o l'asma?  Sì  No
12. Ha alcune indicazioni scritte su come prendersi cura dell'asma del Suo bambino?  Sì  No
13. Il Suo bambino ha mai avuto problemi come starnuti frequenti o naso che cola o naso tappato quando **non** aveva raffreddore o influenza?  Sì  No
14. Negli ultimi 12 mesi, il Suo bambino ha mai avuto problemi come starnuti frequenti o naso che cola o naso tappato quando **non** aveva raffreddore o influenza?  Sì  No

***SE HA RISPOSTO "NO" PER FAVORE VADA ALLA DOMANDA 16***

15. Negli ultimi 12 mesi, questo problema al naso è stato accompagnato da prurito o lacrimazione agli occhi?  Sì  No
16. Il Suo bambino ha mai avuto febbre da fieno?  Sì  No
17. Il Suo bambino ha mai avuto un rossore con prurito che appariva e scompariva per almeno sei mesi?  Sì  No
18. Il Suo bambino ha mai avuto questo rossore con prurito almeno una volta negli ultimi 12 mesi?  Sì  No

***SE HA RISPOSTO "NO" PER FAVORE VADA ALLA DOMANDA 20***

19. Questo rossore è apparso almeno una volta nei seguenti posti:  
le pieghe dei gomiti, dietro le ginocchia,  
di fronte alle caviglie, sotto le natiche,  
o intorno a collo, orecchie ed occhi?  Sì  No
20. Il Suo bambino ha mai avuto l'eczema?  Sì  No
21. Il Suo bambino ha mai fatto un test per le allergie?  Sì  No
22. Se ha risposto "SI", il test era positivo?  Sì  No
23. Il Suo bambino ha mai fatto una vaccinoterapia per prevenire o trattare l'asma?  Sì  No

24. La mamma del bambino fuma o ha mai fumato?

	Ora	Durante il primo anno di vita del bambino	Durante la gravidanza
Sì	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

25. Al momento qualcuno fuma in casa del bambino?  Sì  No

Se sì, quante sigarette al giorno vengono fumate in totale nella casa del bambino?  
(es. La madre ne fuma 4 + il padre ne fuma 5 + altri ne fumano 3 = 12)

- Meno di 10 sigarette   
10 – 20 sigarette   
Più di 20 sigarette

26. La madre del bambino ha mai avuto qualcuna delle seguenti malattie?

- Asma   
Raffreddore da fieno   
Eczema

27. Il padre del bambino ha mai avuto qualcuna delle seguenti malattie?

- Asma   
Raffreddore da fieno   
Eczema

28. In quale nazione è nata la madre del bambino? \_\_\_\_\_

29. In quale nazione è nato il padre del bambino? \_\_\_\_\_

30. Quale è il livello di istruzione dei genitori?

- Madre
- Non ha titoli di studio   
Licenza elementare   
Diploma di scuola media inferiore o avviamento professionale   
Diploma di scuola media superiore   
Laurea   
Altro \_\_\_\_\_

Padre

Non ha titoli di studio

Licenza elementare

Diploma di scuola media inferiore o avviamento professionale

Diploma di scuola media superiore

Laurea

Altro \_\_\_\_\_

31. Chi ha risposto al questionario?  Padre  Madre  Altri

32. Quando è stato compilato questo questionario? \_\_/\_\_/\_\_\_\_

### **1.2.3. Swedish Questionnaire**

## 1.2.3.1. Swedish Adults Questionnaire

### Adult's questionnaire

### IMCA II

### HES Feasibility Study

### (GA<sup>2</sup>LEN screening questionnaire) Adult's questionnaire

Besvara frågorna genom att kryssa i rätt alternativ.



Om Du är osäker vid "nej-ja-frågor", Välj nej-rutan.

NEJ JA

1. Har Du haft pip- eller har det väst i bröstet vid något tillfälle under de senaste 12 månaderna? NEJ JA

*OM SVARET ÄR 'NEJ', GÅ TILL FRÅGA 2, OM 'JA'*

- 1.1 Har Du överhuvudtaget varit det minsta andfådd när Du haft detta pipande ljud? NEJ JA

- 1.2 Har Du haft detta pip eller väsende i bröstet när- Du inte samtidigt varit förkyld? NEJ JA

2. Har Du vaknat med en trånghets känsla i bröstet vid något tillfälle under de senaste 12 månaderna? NEJ JA

3. Har Du vaknat av andnödsattack vid något tillfälle de senaste 12 månaderna? NEJ JA

4. Har Du vaknat av hostattack vid något tillfälle de senaste 12 månaderna? NEJ JA

5. Brukar Du under vintern få upp slem från bröstet nästan varje dag under åtminstone tre månader varje år? NEJ JA

6. Har Du någonsin haft astma? NEJ JA

— **OM 'NEJ' GÅ TILL FRÅGA 7** OM 'JA' GÅ TILL FRÅGA 6.1

ÅLDER

- 6.1 Hur gammal var Du när Du hade Ditt första astmaanfall?  
(Om osäker, ange Din bästa gissning!)
- NEJ JA
- 6.2 Har Du **någonsin** varit inlagd på sjukhus  
på grund av astma?
- NEJ JA
- 6.3 Har Du haft något astmaanfall under  
**de senaste 12 månaderna?**
- NEJ JA
- 6.4 Tar Du **för närvarande** någon **astma**medicin, inklusive  
inhalatorer, sprejer eller tabletter?
- NEJ JA
7. Har Du hösnuva eller någon annan allergisk snuva?  
**OM 'NEJ' GÅ TILL FRÅGA 8 OM 'JA' GÅ TILL FRÅGA 7.1**
- NEJ JA
- 7.1 Har Du haft problem med allergisk snuva  
**under de senaste 12 månaderna?**
- NEJ JA
- 7.2 Har Du någonsin haft problem med allergisk snuva under  
**mer än 4 dagar under en enskild vecka?**
- NEJ JA
- 7.3 **Om ja** hände detta under **mer än 4 veckor i sträck?**
- NEJ JA
8. Har Du varit täppt i näsan i **mer än 12 veckor under de senaste 12 månaderna?**
- NEJ JA
9. Har Du haft värk eller tryck runt pannan, näsan eller ögonen i  
**mer än 12 veckor under de senaste 12 månaderna?**
- NEJ JA
10. Har Du haft missfärgat nässekret (snor) eller missfärgat slem i halsen  
**i mer än 12 veckor under de senaste 12 månaderna?**
- NEJ JA
11. Har Ditt luktsinne varit nedsatt eller borta i **mer än 12 veckor**  
**under de senaste 12 månaderna?**
- NEJ JA
12. Har en läkare **någon gång** sagt att Du har  
**kronisk** bihåleinflammation?
- NEJ JA

13. Har Du någonsin under **minst 6 månader** haft besvär av återkommande kliande utslag?  NEJ  JA  
**OM 'NEJ' GÅ TILL FRÅGA 14** **OM 'JA' GÅ TILL FRÅGA 13.1**

13.1 Har Du haft det kliande utslaget **under de senaste 12 månaderna**?  NEJ  JA

13.2 Drabbar detta **endast** Dina händer?  NEJ  JA

14. Har Du någonsin haft eksem eller någon form av hudallergi?  NEJ  JA

15. Har Du någon gång haft svårt att andas inom 3 timmar efter att Du intagit smärtstillande läkemedel?  NEJ  JA

**OM 'NEJ' GÅ TILL FRÅGA 16** **OM 'JA' GÅ TILL FRÅGA 15.1**

15.1 Vilket läkemedel? .....

16. Har Du någonsin rökt under minst ett års tid?  NEJ  JA

['JA' betyder *minst en cigarett om dagen eller en cigarr i veckan under minst ett år*]

**OM 'NEJ' GÅ TILL FRÅGA 17** **OM 'JA' GÅ TILL FRÅGA 16.1**

16.1 Hur gammal var Du när Du började röka?  ÅLDER

16.2 Har Du rökt alls under **sista månaden**?  NEJ  JA  
**OM 'JA' GÅ TILL FRÅGA 16.3** **OM 'NEJ' GÅ TILL 16.2.1**

16.2.1 Hur gammal var Du när Du slutade röka?  ÅLDER

16.3 **I genomsnitt**, hur mycket röker (rökte) Du?

Cigaretter per dygn

17. Är Du **för närvarande**:

**Kryssa bara i en ruta!**

- |                         |    |                          |
|-------------------------|----|--------------------------|
| anställd                | 1. | <input type="checkbox"/> |
| egen-företagare         | 2. | <input type="checkbox"/> |
| arbetslös               | 3. | <input type="checkbox"/> |
| sjukskriven, sjukbidrag | 4. | <input type="checkbox"/> |
| hemarbetande full tid   | 5. | <input type="checkbox"/> |
| studerande, full tid    | 6. | <input type="checkbox"/> |
| pensionerad             | 7. | <input type="checkbox"/> |
| övrigt                  | 8. | <input type="checkbox"/> |

18. Arbetar Du **för närvarande**:

a. inom sjukvården (t.ex. som sjuksköterska, undersköterska, medicintekniker, läkare, ambulanssjukvårdare eller liknande)?

NEJ

JA



b. i ett jobb som huvudsakligen innefattar någon typ av arbete med rengörning eller städning

NEJ

JA

19 Ange Ditt födelsedatum

DAG

MÅNAD

19 ÅR

20. Ange dagens datum

DAG

MÅNAD

20 ÅR

21. Är Du man eller kvinna?

MAN KVINNA

**Får vi ta kontakt med Dig igen för ytterligare hjälp med projektet eller för att be om ytterligare information?**

NEJ

JA

**TACK FÖR HJÄLPEN!**

## 1.2.3.2. Swedish Children Questionnaire

### IMCA II

### HES Feasibility Study

(Questions selected from the ISAAC II protocol)

#### Barn frågeformulär

1. Är ert barn pojke eller flicka?

*Pojke*

*Flicka*

2. När föddes Ert barn

-----/-----/-----

dd mm år

3. Är ert barn fött i Sverige?

*Ja*

*Nej*

4. Om Nej i vilket land? \_\_\_\_\_

5. Har Ert barn någonsin haft väsande eller pipande andningsljud i bröstet?

*Ja*

*Nej*

Om Ni svarat "NEJ" gå direkt till fråga 10.

6. Har Ert barn haft väsande eller pipande andningsljud i bröstet någon gång under de senaste 12 månaderna?

*Ja*

*Nej*

Om Ni svarat "NEJ" gå direkt till fråga 10.

7. Hur många episoder med väsande andning har Ert barn haft under de senaste 12 månaderna?

*Ingen*

*1 - 3 episoder*

*4 - 12 episoder*

*Fler än 12 episoder*

8. Under de senaste 12 månaderna hur ofta har, i genomsnitt, Ert barns sömn störts av väsande andning?

- Aldrig vaknat med besvär
- Mindre än en två nätter/månad
- Mindre än en natt/vecka
- En-flera nätter/vecka
- Varje eller nästan varje natt per vecka

9. Under de senaste 12 månaderna har Ert barns andning någon gång varit så svår att det endast kunnat säga ett-två ord mellan andetagen?

- Ja
- Nej

10. Har Ert barn någonsin haft astma?

- Ja
- Nej

11. Har Ditt barn använt någon eller några mediciner mot väsende andning eller astma under de senaste 12 månaderna?  Ja  Nej

12. Har Ditt barn fått en skriftlig plan med instruktioner om hur barnets astmabesvär ska behandlas?

- Ja
- Nej

13. Har Ert barn någonsin varit besvärad av *nysningar*, *rinnsnuva* eller *nästäppa utan* att ha varit förkyld?  Ja  Nej

Om Ni svarat "NEJ" gå direkt till fråga 16

14. Har Ert barn under de senaste 12 månaderna varit besvärad av *nysningar*, *rinnsnuva* eller *nästäppa utan* att ha varit förkyld?  Ja  Nej

Om Ni svarat "NEJ" gå direkt till fråga 16

15. Har under de senaste 12 månaderna dessa näsbesvär förekommit samtidigt med *kliande*, *rinnande ögon*?

- Ja
- Nej

16. Har Ert barn någonsin haft "hösnuva"?  Ja  Nej

17. Har Ert barn någonsin haft ett *kliande utslag* som kommit och gått under minst 6 månader?

- Ja
- Nej

18. Har Ert barn haft detta kliande utslag någon gång under de senaste 12 månaderna?

- Ja
- Nej

Om Ni svarat "NEJ" gå direkt till fråga 20.

19. Har detta kliande utslag vid något tillfälle förekommit på något av följande ställen:  
*Armveck, knäveck, fotleder, på lårens baksidor eller på halsen, kring ögonen eller öronen?*

- Ja*  
 *Nej*

20. Har Ert barn någonsin haft "eksem"?  Ja  Nej

21. Har Ert barn någonsin genomgått en allergitest?  Yes  No

22. Om "JA" var testet positivt?  Yes  No

23. Har ditt barn någonsin erhållit allergivaccination eller hyposensibilisering?  Ja  Nej

24. Röker eller rökt barnets mor?

	För närvarande	Under barnets första levnads år	Under graviditeten
Ja	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nej	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

25. Röker någon inomhus i barnets hem?

- Ja*  
 *Nej*

Om ja, hur många cigaretter total röks i genomsnitt per dag i barnets hem

(t.ex. mor 4 + far 5 + annan person 3 = 12)

Mindre än 10 cigaretter

10-20 cigaretter

Mer än 20 cigaretter

26. Har barnets mor någonsin haft någon av följande sjukdomar?

Astma

Hösnuva

Eksem

27. Har barnets far någonsin haft någon av följande sjukdomar?

Astma

Hösnuva

Eksem

28. I vilket land är barnets mor född? \_\_\_\_\_

29. I vilket land är barnets far född? \_\_\_\_\_

30 Hur långutbildningen har barnets föräldrar?

	Mor	Far
Grundskola	_____år	_____år
Gymnasium/högskola	_____år	_____år

31. Vem besvarade formuläret?

- Far   
Mor   
Annand person

32. När besvarades formuläret? \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Dag Mån År

**TACK FÖR HJÄLPEN!**

## **1.2.4. German Questionnaire**

## 1.2.4.1. German Adults Questionnaire

Bitte beantworten Sie die Fragen, indem Sie das zutreffende Kästchen ankreuzen:

Nein  Ja

Wenn Sie nicht sicher sind, wählen Sie bitte ‚Nein‘.

Teilnehmer- ID \_\_\_\_\_

1. Haben Sie jemals **in den letzten 12 Monaten** ein pfeifendes oder brummendes Geräusch in Ihrem Brustkorb gehört?

Nein  Ja

**FALLS „NEIN“ BITTE WEITER MIT FRAGE 2, FALLS „JA“ BITTE WEITER MIT FRAGE 1.1**

1.1 Fühlten Sie sich jemals außer Atem, als dieses pfeifende Geräusch auftrat?

Nein  Ja

1.2 Hatten Sie dieses Pfeifen oder Brummen, wenn Sie nicht erkältet waren?

Nein  Ja

2. Sind Sie irgendwann **in den letzten 12 Monaten** mit einem Engegefühl im Brustkorb aufgewacht?

Nein  Ja

3. Sind Sie irgendwann **in den letzten 12 Monaten** durch einen Anfall von Luftnot aufgewacht?

Nein  Ja

4. Sind Sie irgendwann **in den letzten 12 Monaten** wegen eines Hustenanfalls aufgewacht?

Nein  Ja

5. Haben Sie an den meisten Tagen **für mindestens 3 Monate jährlich** Auswurf?

Nein  Ja

6. Haben Sie **jemals** Asthma gehabt?

Nein  Ja

**FALLS „NEIN“ BITTE WEITER MIT FRAGE 7; FALLS „JA“ BITTE WEITER MIT FRAGE 6.1**

6.1 Wie alt waren Sie, als Sie Ihren ersten Asthmaanfall hatten?  
(wenn Sie unsicher sind, schätzen Sie bitte)

Jahre

6.2 Sind Sie wegen Asthma **jemals** stationär im Krankenhaus behandelt worden?

Nein  Ja

6.3 Hatten Sie **in den letzten 12 Monaten** einen Asthmaanfall?

Nein  Ja

6.4 Nehmen Sie **gegenwärtig** Medikamente gegen **Asthma** ein (einschließlich Inhalationen, Dosieraerosolen (Sprays) oder Tabletten)?

Nein  Ja



- 16.1 Wie alt waren Sie, als Sie anfangen zu rauchen?  Jahre
- 16.2 Haben Sie innerhalb des letzten Monats geraucht?  Nein  Ja

**FALLS „Ja“ BITTE WEITER MIT FRAGE 16.3; FALLS „Nein“ BITTE WEITER MIT FRAGE 16.2.1**

- 16.2.1 Wie alt waren Sie, als Sie das Rauchen aufgegeben haben?  Jahre
- 16.3 Wieviel rauchen (bzw. rauchten) Sie durchschnittlich?  Zigaretten/Tag

17. Sind Sie zur Zeit

**(bitte nur ein Kästchen ankreuzen!)**

- a) angestellt
- b) selbständig
- c) arbeitslos
- d) aus gesundheitlichen Gründen nicht arbeitend
- e) Hausfrau / Hausmann (hauptberuflich)
- f) Student (hauptberuflich)
- g) pensioniert / berentet
- h) sonstiges

18. Arbeiten Sie zur Zeit:

- a) im Gesundheitsdienst (z.B. als Krankenschwester, Technischer Assistent, Arzt, Rettungsassistent, oder ähnliches)?  Nein  Ja
- b) in einem Job, in dem Sie hauptsächlich mit irgendwelchen Reinigungsarbeiten beschäftigt sind?  Nein  Ja

**German specific questions removed**

21. Wann wurden Sie geboren?  Tag  Monat  Jahr

22. Welches Datum ist heute?  Tag  Monat  Jahr

23. Sind Sie männlich oder weiblich?  männlich  weiblich

24. Dürfen wir Sie zu einem späteren Zeitpunkt erneut kontaktieren, damit Sie uns bei dieser Forschung weiter helfen können und um Ihnen gegebenenfalls weitere Informationen hierüber zu geben?  Nein  Ja

## 1.2.4.2. German Children Questionnaire

### IMCA II HES Feasibility Study Kinderfragebogen

Teilnehmer- ID \_\_\_\_\_

- 1 Ist Ihr Kind ein Junge oder ein Mädchen ?  Junge  Mädchen
- 2 Geburtsdatum Ihres Kindes  |  |   
Tag / Monat / Jahr
- 3 Ist Ihr Kind in Deutschland geboren?  Ja  Nein  
Wenn nein, in welchem Land ist es geboren \_\_\_\_\_
- 4 Hatte Ihr Kind irgendwann einmal beim Atmen pfeifende oder keuchende Geräusche im Brustkorb?  Ja  Nein  
falls nein, bitte weiter mit Frage 9!
- 5 Hatte Ihr Kind in den letzten 12 Monaten beim Atmen pfeifende oder keuchende Geräusche im Brustkorb?  Ja  Nein  
falls nein, bitte weiter mit Frage 9!
- 6 Wie viele Anfälle von pfeifender oder keuchender Atmung hatte Ihr Kind in den letzten 12 Monaten?  
keinen Anfall .....   
1 - 3 Anfälle .....   
4 - 12 Anfälle .....   
mehr als 12 Anfälle .....
- 7 Wie oft ist Ihr Kind im Durchschnitt in den letzten 12 Monaten wegen pfeifender oder keuchender Atmung aufgewacht?  
nie deswegen aufgewacht .....   
weniger als zwei Nächte pro Monat .....   
weniger als eine Nacht pro Woche .....   
eine oder mehrere Nächte pro Woche .....   
jede Nacht oder die meisten Nächte in der Woche .....

- 8 War die pfeifende oder keuchende Atmung in den **letzten 12 Monaten** jemals so stark, dass Ihr Kind beim Reden schon nach ein oder zwei Worten wieder Luft holen musste?  Ja  Nein
- 9 Hatte Ihr Kind **irgendwann einmal** Asthma?  Ja  Nein
- 10 Hatte Ihr Kind **irgendwann einmal** Niesanfalle oder eine laufende, verstopfte oder juckende Nase, obwohl es **nicht** erkaltet war?  
falls nein, bitte weiter mit Frage 13!  Ja  Nein
- 11 Hatte Ihr Kind in den **letzten 12 Monaten** Niesanfalle oder eine laufende, verstopfte oder juckende Nase, obwohl es **nicht** erkaltet war?  
falls nein, bitte weiter mit Frage 13!  Ja  Nein
- 12 Hatte Ihr Kind in den **letzten 12 Monaten** gleichzeitig mit diesen Nasenbeschwerden juckende oder tranende Augen?  Ja  Nein
- 13 Hatte Ihr Kind **irgendwann einmal** Heuschnupfen?  Ja  Nein
- 14 Hatte Ihr Kind **irgendwann einmal** einen juckenden Hautausschlag, der starker oder schwacher ber mindestens 6 Monate auftrat?  
falls nein, bitte weiter mit Frage 17!  Ja  Nein
- 15 Trat dieser juckende Hautausschlag bei Ihrem Kind auch in den **letzten 12 Monaten** auf?  
falls nein, bitte weiter mit Frage 17!  Ja  Nein
- 16 Trat dieser juckende Hautausschlag bei Ihrem Kind **irgendwann einmal** an einer der folgenden Krperstellen auf: In den Ellenbeugen oder Kniekehlen, an den Hand- /oder Fugelenken, im Gesicht, am Hals?  Ja  Nein
- 17 Hatte Ihr Kind **irgendwann einmal** Neurodermitis (atopisches Ekzem, endogenes Ekzem, atopische Dermatitis)?  Ja  Nein
- 18 Hat Ihr Kind in den **letzten 12 Monaten** irgendwelche Medikamente (Safte, Tabletten oder Sprays) gegen o.g. Atembeschwerden (pfeifende oder keuchende Atmung) oder Asthma bekommen?  Ja  Nein
- 19 Haben Sie schriftliche Anleitungen, wie Sie diese Atembeschwerden behandeln sollen?  Ja  Nein

20 Ist Ihr Kind jemals auf Allergien getestet worden?  Ja  Nein

falls ja → War dieser Test positiv?  Ja  Nein

21 Ist ihr Kind jemals gegen eine Allergie desensibilisiert/hyposensibilisiert worden, um Asthma vorzubeugen oder zu behandeln (dabei bekommt man regelmäßig Spritzen)  Ja  Nein

22 Raucht/rauchte die Mutter des Kindes?  
(Mehrere Antworten sind möglich)

	zur Zeit	im ersten Lebensjahr	während der Schwangerschaft
ja	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
nein	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

23 Wird zur Zeit in der Wohnung, in der Ihr Kind lebt, geraucht?  Ja  Nein

falls ja → Wie viele Zigaretten werden insgesamt durchschnittlich pro Tag in dieser Wohnung geraucht?  
(z.B. Mutter raucht 4 + Vater raucht 5 + sonstige Person raucht 3 = 12 Zigaretten)

	zur Zeit	im dritten Lebensjahr	im ersten Lebensjahr
bis 10 Zigaretten	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10 - 20	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
mehr als 20	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24 Hatte die leibliche Mutter des Kindes irgendwann einmal folgende Erkrankungen

Asthma	<input type="checkbox"/> Ja	<input type="checkbox"/> Nein
Heuschnupfen	<input type="checkbox"/> Ja	<input type="checkbox"/> Nein
Neurodermitis (atopisches Ekzem, endogenes Ekzem, atopische Dermatitis)?	<input type="checkbox"/> Ja	<input type="checkbox"/> Nein

25 Hatte der leibliche Vater des Kindes irgendwann einmal folgende Erkrankungen

Asthma	<input type="checkbox"/> Ja	<input type="checkbox"/> Nein
Heuschnupfen	<input type="checkbox"/> Ja	<input type="checkbox"/> Nein
Neurodermitis (atopisches Ekzem, endogenes Ekzem, atopische Dermatitis)?	<input type="checkbox"/> Ja	<input type="checkbox"/> Nein

26 In welchem Land ist die leibliche Mutter des Kindes geboren? \_\_\_\_\_

27 In welchem Land ist der leibliche Vater des Kindes geboren? \_\_\_\_\_

28 Welches ist der höchste Schul- bzw. Hochschulabschluß der Erziehungsberechtigten?

	Mutter	Vater
kein Abschluss.....	<input type="checkbox"/>	<input type="checkbox"/>
Hauptschule/Volksschule.....	<input type="checkbox"/>	<input type="checkbox"/>
Mittlere Reife/Realschule.....	<input type="checkbox"/>	<input type="checkbox"/>
Abitur/Fachabitur.....	<input type="checkbox"/>	<input type="checkbox"/>
Hochschule/Fachhochschule/Universität.....	<input type="checkbox"/>	<input type="checkbox"/>
sonstiger Abschluss.....	<input type="checkbox"/>	<input type="checkbox"/>

29 Wer hat diesen Fragebogen beantwortet?

*(Mehrere Antworten sind möglich)*

Vater.....	<input type="checkbox"/>
Mutter.....	<input type="checkbox"/>
sonstige Person.....	<input type="checkbox"/>

30 Wann wurde dieser Fragebogen beantwortet?

\_\_/\_\_/\_\_\_\_  
Tag / Monat /Jahr

## **1.3. Measurements to perform**

## **1.4. Study Information Sheet to Participants**

### 1.4.1. Adults

#### Information sheet about the questionnaire and other measurements to be performed in this study

(Adults/English)

In this information sheet it is described what implies the study participation and in each paragraph you will find a description of each measurement suggested to perform to you.

Before any of the measurements suggested are performed, you will have to sign the consent form. We really would like you to participate in all measurements, however you always will have the opportunity to decide to authorize all measurements or alternatively select just some of them. At any stage, including after having signed the consent form you will have the opportunity to withdraw from the study.

- 1. Questionnaire:** The fieldworker nurse/doctor will contact you and explain in detail the type of questions included in the questionnaire and will tell you the time required to complete the interview. The questionnaire is brief and basically are questions aiming to know your respiratory health.
- 2. Weight and height:** In order to measure your weight an automatic scale that transmit the data to a portable computer automatically via Bluetooth will be used. Your height will be measured manually.
- 3. Respiratory test – Spirometry:** This is a test aiming to measure your breathing capacity and it is known as spirometry. This is a relatively easy test and the nurse will ask your son/daughter to blow several times through a tube connected to an instrument that will measure your capacity to breathe. This test does not imply any pain or discomfort.
- 4. Pulseoximetry:** This is an easy test that will consist in putting a clip in one finger of your son/daughter that directly measures the pulse and oxygen saturation in blood.
- 5. Blood pressure:** This is a well known and easy test. It does not produce any pain or discomfort. This will consist in putting an armband in the arm of your son/daughter connected to an instrument that automatically measures blood pressure.
- 6. Blood extraction:** This is a measurement necessary to know if some blood indicators related to your respiratory health are abnormal. This is a measurement that may cause little discomfort but it is not painful. In order to reduce any possible discomfort, before to perform the venipuncture an anesthetic cream will be applied.

## 1.4.2. Children

### Information sheet about the questionnaire and other measurements to be performed in this study (Children/English)

In this information sheet it is described what implies the study participation and in each paragraph you will find a description of each measurement suggested to perform to you son/daughter.

Before any of the measurements suggested are performed, you in agreement with your son/daughter have to sign the consent form. We really would like your child to participate in all measurements, however you always will have the opportunity to decide to authorize all measurements or alternatively select just some of them. At any stage, including after having signed the consent form you will have the opportunity to withdraw from the study.

- 1. Questionnaire:** The fieldworker nurse/doctor will contact you and explain in detail the type of questions included in the questionnaire and will tell you the time required to complete the interview. The questionnaire is brief and basically are questions aiming to know your respiratory health.
- 2. Weight and height:** In order to measure your weight an automatic scale that transmit the data to a portable computer automatically via *Bluetooth* will be used. Your height will be measured manually.
- 3. Respiratory test – Spirometry:** This is a test aiming to measure your breathing capacity and it is known as spirometry. This is a relatively easy test and the nurse will ask your son/daughter to blow several times through a tube connected to an instrument that will measure your capacity to breathe. This test does not imply any pain or discomfort.
- 4. Pulseoximetry:** This is an easy test that will consist in putting a clip in one finger of your son/daughter that directly measures the pulse and oxygen saturation in blood.
- 5. Blood pressure:** This is a well known and easy test. It does not produce any pain or discomfort. This will consist in putting an armband in the arm of your son/daughter connected to an instrument that automatically measures blood pressure.
- 6. Blood extraction:** This is a measurement necessary to know if some blood indicators related to your respiratory health are abnormal. This is a measurement that may cause little discomfort but it is not painful. In order to reduce any possible discomfort, before to perform the venipuncture an anesthetic cream will be applied.

## **1.5. Study Participation Consent Form**

### 1.5.1. Adults

## CONSENT FORM

(ADULTS/ENGLISH)

### Study on new methods to evaluate respiratory health in the community

I, ..... accept to participate in the study on new methods to evaluate respiratory health in the community. I understand participation is voluntary and at any stage I can withdraw from the study without any explanation. The fieldworker/nurse/doctor has informed me about the questionnaire and I have read in detail the information about other measurements confirming I accept to participate in the study performing all items marked below:

a) The questionnaire and all described measurements.....

b) The questionnaire and all measurements marked below:

Weight and height.....

Respiratory test (spirometry) .....

Pulseoximetry .....

Blood pressure .....

Blood extraction.....

c) Only the questionnaire.....

Signed: .....

(Adult participant >18 years old)

(City-Date), .....

**IMPORTANT:** In case any measurement detects a health problem would you like to receive the results in order to be able to discuss them with your general practitioner.

Please, in case your answer is positive mark it here .....

## 1.5.2. Children

### CONSENT FORM

(CHILDREN/ENGLISH)

#### Study on new methods to evaluate respiratory health in the community

I, ..... allow my son/daughter (Name:.....) to participate in the study on new methods to evaluate respiratory health in the community. I understand participation is voluntary and at any stage we can withdraw from the study without any explanation. The fieldworker/nurse/doctor has informed me about the questionnaire and we have read in detail the information about other measurements confirming we accept to participate in the study performing all items marked below:

a) The questionnaire and all described measurements.....

b) The questionnaire and all measurements marked below:

Weight and height.....

Respiratory test (spirometry) .....

Pulseoximetry .....

Blood pressure .....

Blood extraction.....

c) Only the questionnaire.....

Signed: .....  
(Father/mother/tutor of participants <18 years old)

(City-Date), .....

**IMPORTANT:** In case any measurement detects a health problem would you like to receive the results in order to be able to discuss them with your general practitioner.

Please, in case your answer is positive mark it here .....

## **1.6. First Contact Letter for Study Performance**

## 1.6.1. First Contact Letter: Adults

### Estudio sobre nuevos métodos de evaluar la salud respiratoria en la comunidad

Apreciado Sr./a

El equipo de investigación del Institut de Prestacions d'Assistència Mèdica al Personal Municipal (PAMEM) en colaboración con el Institut Municipal d'Investigació Mèdica (IMIM) y el Hospital Clínic i Provincial de Barcelona están desarrollando el estudio Europeo IMCA II que pretende mejorar el conocimiento actual sobre la epidemiología de las enfermedades respiratorias.

Uno de los **objetivos** de este proyecto es **desarrollar nuevos métodos de medida de los problemas de salud respiratoria a nivel de la población general** utilizando las nuevas tecnologías de la información que permitan realizar la recogida y transmisión de datos desde el lugar donde se realizan las pruebas de forma inmediata.

Con motivo de poder probar la tecnología desarrollada por el equipo de investigación y tener mejor conocimiento de las enfermedades respiratorias en la población del área de influencia del **CAP Larrard**, el equipo investigador en colaboración con la Dirección Asistencial de este centro ha diseñado y decidido llevar a cabo un estudio piloto en el que participan personas adscritas en el centro. Para poder llevar a cabo el estudio le pedimos que lea atentamente esta carta y que considere su colaboración.

La participación en este estudio significa responder a unas preguntas de un **cuestionario** sobre salud respiratoria y también la **realización de unas pruebas** que nos ayudaran a identificar mejor los problemas de salud y así también poder informar de los resultados a las personas participantes. En la hoja adjunta encontrará la descripción de las pruebas propuestas a realizar. Idealmente, nos gustaría poder realizarle todas las pruebas pero si hay alguna que no desee realizarla, usted siempre podrá decidir libremente cual no quiere hacer. Tanto las preguntas del cuestionario como las pruebas detalladas serán realizadas por enfermeras del CAP Larrard y la **participación en el estudio significará únicamente estar disponible una hora de su tiempo.**

Con tal de poder confirmar su voluntad de participar en el estudio y también para informarle con más detalle sobre el cuestionario, las pruebas a realizar y donde se realizarán, **una enfermera del CAP Larrard en breve le/la telefonará.** Durante esta llamada, usted tendrá la oportunidad de preguntar cualquier duda sobre el estudio y confirmar o negar la participación en el estudio.

La realización de este estudio nos permitirá conocer mucho mejor los problemas de salud respiratoria en nuestro medio, diseñar programas de prevención y de mejora de la atención sanitaria y, en definitiva mejorar la calidad de vida de nuestra población.

Esperamos poder contar con su participación y que los pequeños inconvenientes de contestar las preguntas del cuestionario y el tiempo para la realización de las pruebas sean compensados por los nuevos conocimientos que aportará el estudio.

Cordialmente,

Dr Enric Duran  
Coordinador de l'estudi

Dr. Xavier Sibera  
Director CAP Larrard

Dr. Josep Farrés  
Conseller Delegat de PAMEM

## 1.6.2. First Contact Letter: Children

### Estudio sobre nuevos métodos de evaluar la salud respiratoria en la comunidad

Apreciado Sr./a

El equipo de investigación del Institut de Prestacions d'Assistència Mèdica al Personal Municipal (PAMEM) en colaboración con el Institut Municipal d'Investigació Mèdica (IMIM) y el Hospital Clínic i Provincial de Barcelona están desarrollando el estudio Europeo IMCA II que pretende mejorar el conocimiento actual sobre la epidemiología de las enfermedades respiratorias.

Uno de los **objetivos** de este proyecto es **desarrollar nuevos métodos de medida de los problemas de salud respiratoria a nivel de la población general** utilizando las nuevas tecnologías de la información que permitan realizar la recogida y transmisión de datos desde el lugar donde se realizan las pruebas de forma inmediata.

Con motivo de poder probar la tecnología desarrollada por el equipo de investigación y tener mejor conocimiento de las enfermedades respiratorias en la población del área de influencia del **CAP Larrard**, el equipo investigador en colaboración con la Dirección Asistencial de este centro ha diseñado y decidido llevar a cabo un estudio piloto en el que participan personas adscritas en el centro (incluyendo niños/as y adultos). Para poder llevar a cabo el estudio le pedimos que lea atentamente esta carta y que considere la colaboración de su hijo/a participando en el estudio.

La participación en este estudio significa que usted tendrá que responder a unas preguntas de un **cuestionario** sobre salud respiratoria de su **hijo/a** y también decidir conjuntamente con el/ella la autorización para la **realización de unas pruebas** que nos ayudaran a identificar mejor los problemas de salud y así también poder informar de los resultados a las personas participantes. En la hoja adjunta encontrará la descripción de las pruebas propuestas a realizar. Idealmente, nos gustaría poder realizarle todas las pruebas pero si hay alguna que no desean hacerla usted y su hijo/a, siempre podrán decidir libremente cual no quieren hacer. Tanto las preguntas del cuestionario como las pruebas detalladas serán realizadas por enfermeras del CAP Larrard y la **participación en el estudio significará** únicamente que su hijo/a tendrá que estar disponible **una hora de su tiempo acompañado/a po el padre, madre o tutor.**

Con tal de poder confirmar su voluntad de participar en el estudio y también para informarle con más detalle sobre el cuestionario, las pruebas a realizar y donde se realizarán, **una enfermera del CAP Larrard en breve le/la telefonará.** Durante esta llamada, usted tendrá la oportunidad de preguntar cualquier duda sobre el estudio y confirmar o negar la participación en el estudio.

La realización de este estudio nos permitirá conocer mucho mejor los problemas de salud respiratoria en nuestro medio, diseñar programas de prevención y de mejora de la atención sanitaria y, en definitiva mejorar la calidad de vida de nuestra población.

Esperamos poder contar con su participación y que los pequeños inconvenientes de contestar las preguntas del cuestionario y el tiempo para la realización de las pruebas sean compensados por los nuevos conocimientos que aportaran el estudio.

Cordialmente,

Dr Enric Duran  
Coordinador de l'estudi

Dr. Xavier Sibera  
Director CAP Larrard

Dr. Josep Farrés  
Conseller Delegat de PAMEM

## **2. Technological tools and equipment for study performance**

## 2.1. Laptop computer

The computer used in the IMCA II project is a Laptop Acer TravelMate 6292 model.

The TravelMate 6292 is positioned for on-the-go business users who demand security and reliability, with a range of essential features: wireless connectivity, video conferencing capabilities, Acer Empowering Technology, and others, to ensure maximum efficiency and productivity. Data security is specifically addressed by the design of the TravelMate 6292. The integrated Acer Bio-Protection fingerprint reader gives you additional peace-of-mind with the assurance that your confidential information is protected, no matter where you go.



This is a very important aspect for our confidentiality's data and for our fieldworkers that they have to do the interviews in the participants home and they have the possibility to loss the equipment during the different visits.

The Acer Bio-Protection fingerprint solution increases network and data security by verifying your true identity. The fingerprint solution replaces password security with finger swipe to safeguard valuable notebook assets and ensure data integrity.

<http://www.ipwireless.com/technology/>

## 2.2. Sensors for measurements performance

### 2.2.1. Blood pressure

The blood pressure sensor used in the IMCA II project is the *Digital Blood Pressure Monitor UA-767BT de A&D Medical*. The "Instruction Manual: Digital Blood Pressure Monitor to AND" is available in English, French, Spanish, Italian, Deutsch, Nederland and Chinese and you can find this manual in the next web address: <http://www.andmedical.com>



For the correct use with the sensor you have to follow the next steps:

1. Follow the aspects and steps of blood pressure measurement in relation to the technique and the procedure.
2. Place the cuff on the arm (preferably the left arm). Sit quietly during measurement.

3. Press the START button. The last data of systolic and diastolic pressure and pulse rate are displayed briefly. Then the display changes as the measurement begins. The cuff starts to inflate. Next, to activate the button "leer" or "read" of the MHWorld questionnaire/sensors to activate the bluetooth.

**Note:** If you wish to stop inflation at any time, press the START button again.

4. When inflation is complete, deflation starts automatically and the ♥ (heart mark) blinks, indicating that the measurement is in progress. Once the pulse is detected, the mark blinks with each pulse beat.

**Note:** If an appropriate pressure is not obtained, the device starts to inflate again automatically.

5. When the measurement is complete, the systolic and diastolic pressure readings and pulse rate are displayed. The cuff exhausts the remaining air and deflates completely.

6. Press the START button again to turn off the power.

**Note:** Model UA-767 BT is provided with an automatic power shut-off function. Allow at least ten minutes between measurements on the same person.

7. The duration to obtain the results of the measurement is more or less 40-50 seconds.

## 2.2.2. Pulsioximetry

To know the oxygen saturation and the pulse we will use the *NONIN 4100 Avant Bluetooth sensor*.

For the correct use with the sensor you have to follow the next steps:

1. Follow the aspects and steps of oxygen saturation and pulse measurement in relation to the technique and the procedure.

2. Turning on the pulsioximeter. Attaching the sensor to the connector turns on the pulsioximeter. There are no switches or buttons to press.

3. Removed the participant's finger into the pulsioximeter.

4. Following, activate the button "leer" or "read" of the MHWorld questionnaire to activate the *Bluetooth*.

5. The duration to obtain the results of the measurement is more or less 90 seconds.

6. You can find more information in the "*Instruction Manual: NONIN 4100 Avant Bluetooth sensor*" that is available in the next website: [www.nonin.com](http://www.nonin.com)

7. Do not perform spirometry if the pulse rate is >120 beats/minutes.



**Note:** Per a la correcta medició de la saturació d'oxigen i freqüència cardíaca s'ha de realitzar prèviament a la realització de l'espirometria i el participant ha d'estar en repòs 5 minuts previs a la mesura.

### 2.2.3. Weight

The weight is determined with the sensor *A&D Medical model UC-321PL*.

For the correct use with the sensor you have to follow the next steps:

1. Press the measurement switch gently.
2. Wait until the "O" symbol is displayed.
3. Step on the scale gently and stand during measurement.
4. Following, activate the button "Leer" or "read" of the MHWorld questionnaire to activate the *Bluetooth*.
5. The participant's weight is displayed after the "O" symbol is displayed.
6. Step off scale.
7. At the end of the measurement, the participant's weight will be sent automatically to the health monitoring device. You do not need to do anything.
8. The duration to obtain the results of the measurement is more or less 90 seconds.



The "*Instruction Manual: A&D Medical model UC-321PL*" is available in English and Spanish version. You can find this manual in the next website: <http://www.andmedical.com>

**Note:** It is recommended that the scale be used on a solid level surface, such as tile, wood, or laminate flooring. If the scale must be used on a carpet, be sure to attach the plastic feet.

#### **2.2.4. Spirometry**

The pulmonary function is determined with the sensor EasyOne Model 2001.

For the correct use with the sensor you have to follow the next steps:

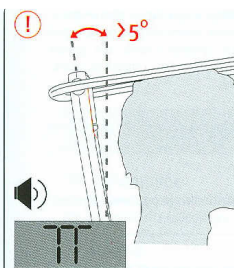
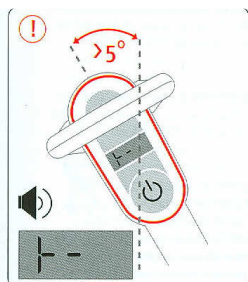
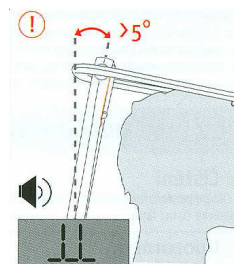
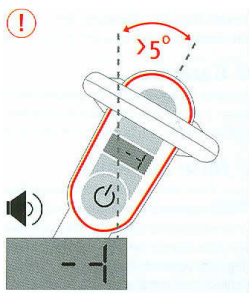
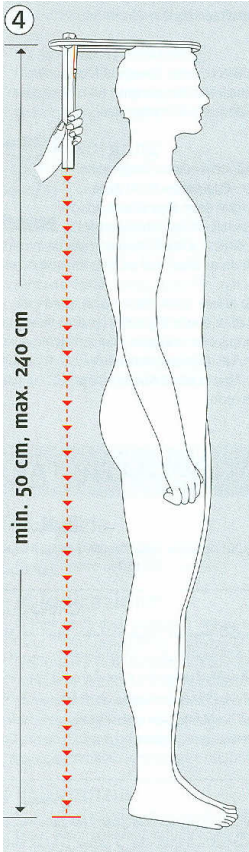
1. Follow the aspects and steps for the procedure spirometry manoeuvre: prepare the participant, instruct and demonstrate the test to the participant, perform manoeuvre, etc.
2. Connect the spirometry in its Bluetooth base when the result of the participant are correct and acceptable for the devices.
3. At the end of the measurement, the participant's results will be sent automatically to the health monitoring device.

For more technical information: [www.ndd.ch](http://www.ndd.ch)

## 2.2.5. Automatic Stadiometer

The height is determined with the *body height meter by Soehnle Professional Height Rod*. For the correct use with the device you have to follow the next steps:

1. Follow the aspects and steps for the procedure to determine the height.
2. Press the measurement switch gently.
3. Obtain the results following the images.
4. You can find more information about the devices in the website:  
[www.soehnle-professional.com](http://www.soehnle-professional.com)



### **3. Fungible material required for blood extraction**

### 3.1. Blood sample: Equipment required for the blood sample in Barcelona.

- Tourniquet
- Vacutainer system with an appropriately sized needle
- Plastic tube holder
- Chlorhexidine in 70% alcohol
- Low-linting swabs
- Sterile adhesive plaster or hypoallergenic tape
- Gloves
- Specimen form and requisition form
- Sharps bin



**Note:** this is the equipment used in the fieldwork in Barcelona.

## **4. Fungible Material Required for Spirometry Performance**

## 4.1. Aerochamber

*Aerochamber* is the chamber used in the IMCA II project to realise the post bronchodilator test.



### Directions for Use

1. Remove cap(s).
2. Look for foreign objects.
3. Insert inhaler (MDI) into back.
4. Apply mask to face or put mouthpiece into mouth.
5. Depress inhaler (MDI) at beginning of slow inhalation. Maintain good seal for 5 breaths after depressing inhaler.
6. Slow down inhalation if you hear the *FLOWSiGnal*\* whistle sound.

### Cleaning Instructions

To clean the Aerochamber you can use the next products:

1. Instrumet FA (dilution to clean the material): 15 minuts
2. Instrumet esporicida (dilution to clean the material): 20 minuts
3. Instrumet Glutaraldehyd 2% (dilution to clean the material): 15 minuts.

You can find more information in the next website:

[http://www.trudellmed.com/Consumers/cn\\_aerochamber\\_plus\\_vhc\\_instructions.asp](http://www.trudellmed.com/Consumers/cn_aerochamber_plus_vhc_instructions.asp)

## 4.2. Spirette mouthpieces



## 4.3. Pinza nasal

## 4.4. Salbutamol – Almerol

## **5. General Overview and Recommendations for Fieldwork Organization**

## **5.1. Organization**

In this chapter you can find the documentation about the pilot study organization in Barcelona.

This is the information about the HES Feasibility Study in Barcelona that is to say the pilot to assess the feasibility of using the MH World system as a tool for performing interviews and measurements at home in the context of large scale respiratory surveys at national and international level and to evaluate to what extent the MH World system can improve response rates to questionnaires, the acceptability of measurements performance and biological samples collection when the measurements are performed at home in comparison to other settings such as a primary health care centre.

## **5.2. Study presentation for the Participants Centres**

First off all, we created systems alliances with the Primary Health Care Centre (PHCC) interested in the project participation. This systems alliances have been created with the PHCC managers (doctors and nurses managers) and during a personal interview.

When the PHCC were contracts, the next step was to contract the IMCA staff. In Barcelona the IMCA staff are nurses for the two roles existing, i.e. the phone operator and the fieldworker.

## **5.3. Content & Objectives of the Study Presentation**

The general presentation is a brief study presentation with a global vision of the project, describing the technology used and the study protocol. Its principal objective is to present and to inform about the IIMCA II project and to inform about the HES Feasibility study in Barcelona.

## **5.4. Acceptation from Participation**

Subsequently to the general presentation, we employed at staff to work in the project, distributing the roles according:

1. their interview ability and interpersonal skills,
2. their knowledge of the assigned geographical area
3. their experience in organizing home visits and performing home visits
4. their Knowledge and skilled in: spirometry test (adults and children), blood sample extraction (adults and children) and clinical interview
5. their familiarity with the new technologies

## **5.5. Staff in Barcelona**

The staff in Barcelona is composed by two phone operator, four field workers and a study manager.

The phone operator is the person who invites individuals to participate in the study, confirms the participation and schedule a visit and makes a short interview with all participants.

The fieldworker is a nurse who phones to the participants to confirm or cancel the visit, performs the interviews either at home or in the health care centre and synchronizes the SVA (survey application) with the BEA (backend application) in order to transmit data to the central server.

The study manager is the person who organises and coordinates the fieldwork.

## **5.6. Time coverage for the fieldwork**

The nurses employed in Barcelona for the fieldwork are primary care nurses. They work in a Primary Health Care Centre on the one hand and work part time for the project on the other hand. We have tried to cover the maximum time coverage, as wide as possible. The first visit started at 8:30 am and the last visit finalized at 21:00 pm.

## **5.7. Sample selection**

In Barcelona, we choosed the model A of the HES Feasibility Study protocol: a randomised control trial.

The geographical area coincided with the catchment's area of PHCC Larrard, a primary health care centre.

The total sample included 250 participants from a population of around 42,000.

The 250 individuals were selected by age and sex and assigned to two groups:

- Group A: For which the interview & measurements will be performed in a health care centre.
- Group B: For which interview & measurements will be performed at home.

In these two groups, the interviews are being coordinated by two phone operators and they are being implemented by four field workers.

We started with group A. This was followed by group B.

You can find more details about the geographical area in the study protocol document.

We made the sample selection using Stata SE v.8. The participants selected with mistakes in their personal and administrative data were removed from the participant list. The participant list was distributed by age groups:

- ❑ Group 1: age between 6 to 10
- ❑ Group 2: age between 11 to 20
- ❑ Group 3: age between 21 to 30
- ❑ Group 4: age between 31 to 40
- ❑ Group 5: age between 41 to 50
- ❑ Group 6: age between 51 to 60
- ❑ Group 7: age between 61 to 70
- ❑ Group 8: age between 71 to 80
- ❑ Group 9: age between 81 to 90
- ❑ Group 10: More than 91

Finally, we had two groups with a total of 125 participants each and stratified by age.

1. The first group – Study Group A – consisted of 125 participants and was divided by the phone operators in two groups. One reason was that because the two phone operators worked at the same time, they might have called the same participant at the same time. Another reason is that with this distribution the phone operator's had the same work load and rhythm.
2. The second group – Study Group B (home visits) – consisted of 125 participants and was divided into two geographical sub-areas ('left' and 'right'). During that time, the two phone operators worked together as a team, coordinating all interviews and participant lists:
  - a. During first 2 weeks all field workers worked together in the left area.
  - b. During the next 2 weeks they work in the right area.
  - c. The 5th week they wentt back to left are for interviewing participants that could not be interviewed in the previous weeks

Why did we start for with group A? There are, basically, two reasons:

1. To become familiar with the new technologies.
2. To determine the average time per visit, with the questionnaire and the measurements

## 5.8. Participant List

The system requires a specific format for data entry, this format is txt. With comma and without space.

For example:

```
045,abc1,Juan,Lopez,Moral,Street,Balmes,50,8c,Barcelona,08001,Spain,110,932930000
046,abc2,Juan1,Lopez1,Moral1,Street,Balmes,50,8c,Barcelona,08001,Spain,110,932930000
047,abc3,Juan2,Lopez2,Moral2,Street,Balmes,50,8c,Barcelona,08001,Spain,110,932930000
```

Utility and importance of the Identification Code:

1. To distribute the interviews: at home or in a health care centre.
2. To distribute the participants between the field workers.
3. To distribute the participants between the phone operators.

It's very important to follow exactly this format for entering the participants list and you should only introduce the participant list with previously verified data, because otherwise if you entry a participant list in the system with their erroneous data you can not longer extract and correct them afterwards (see "The MHWorld: User Manual" for further information).

In Barcelona we used 100 from 199 and specifically, 110 and 120.

- ❑ The 1st digit is the country digit: 1= Barcelona
- ❑ The 2nd digit is Home visits o Primary Health Care Centre: 1=Home visits and 2= Primary Health Care Centre
- ❑ The 3rd digit is for the field workers. In Barcelona we don't use it. This digit is perfect to distribute the participants in different field workers that they are working in different areas. And this distance is so big.

In German, they will use the Identification Code: 200 from 299.

In Sweden, they will use the Identification Code: 300 from 399.

In Italy Roma, they will use the Identification Code: 400 from 499.

In Italy Pisa, they will use the Identification Code: 500 from 599.

Below, we described all of the fields of the participant list:

- ❑ Participant Code; maximum 15 characters , i.e.: 12345
- ❑ Personale Identifier Code; maximum 20 characters
- ❑ Name: maximum 30 characters
- ❑ 1rst Surname: maximum 30 characters

- ❑ 2nd Surname: maximum 30 characters
- ❑ Type of via, i.e.: street, avenue, , square,.... maximum 10 characters
- ❑ Street name: maximum 40 characters
- ❑ Street number: maximum 10 characters
- ❑ Flat number: maximum 10 characters
- ❑ City: maximum 40 characters
- ❑ Post code: maximum 10 characters
- ❑ Country: maximum 30 characters
- ❑ Area Code or Geographical Area Code: maximum 30 characters
- ❑ Telephone number: maximum 20 characters

## **6. Tasks and role of the study manager in each country**

## 6.1. Preparation of the equipment for the fieldwork

When the study manager receives the equipments the first think to do will be:

- ❑ To install the internet connexion of your country.
- ❑ To ensure the username and the password to each user; specially the Study manager and the System administrator.
- ❑ To include/Inclusion the news user at the MHWorld system: field workers and phone operators.
- ❑ Ensure the correct questionnaire's translation.
- ❑ Ensure the correct use of each sensor with one test or patient prove. For this step you have enter a prove participant with the "import participant list" label following the correct format (txt. format). It's necessary prove the sensor, the questionnaire and the synchronization action.
- ❑ To send required information about your fieldwork and, confirmation and correct use about your equipments.

The next step is to create a New Study using the questionnaire in your own language and assigning your own phone operators to your "New Study". When you will enter the name of the Study ("Name"), for a global organization we recommend the following title: "Name of your country" + "HES Feasibility", for instance; "Barcelona HES Feasibility" or "Germany HES Feasibility". You can find the next steps to create an Study in "The MHWorld User Manual".

## **7. Tasks and role of the phone operator/s**

## **7.1. The phone call protocol**

In order to make sure that all the phone operators follow the same steps for contacting the participant, we have elaborated a "Phone Call Protocol".

1. The phone operator calls until 8 times to the participant, if the participant doesn't respond.
2. These 8 phone calls will be in different time/hours so that there are more opportunities to find the participant.
3. Four phone calls will be made during the morning first and the rest during the afternoon.
4. The phone call time slots will be between the 8:00 am. to 21:00 pm.
5. If the phone operator have realized the 8 phone calls and don't manage to get in touch with the participant, then he or she will be replaced by another participant.
6. The information about the phone calls is collected in a access data base, that was designed for the phone operators. (The access data base will be sent to the partners in charge of the feasibility study)

## **7.2. The Phone operator protocol in Barcelona.**

The phone operator has the participants list that is divided in two groups: group A; for which the interview and the measurements will be performed at home and group B; for which the interview and the measurements will be performed in the primary health care centre.

The phone operator role and functions are:

1. To invite individuals to participate in the study
2. To confirm the participation in the study and to schedule a visit
3. To make a short interview with all participants

And the professional profile requirements are:

1. Interview ability and interpersonal skills
2. Knowledge of the geographical area assigned
3. Experience in home visits organization

The phone operator starts with a call to the participant. He or she explains to the participant: the study general information, the consent form and the questionnaire and measurements. Thereafter, the phone operator will schedule a visit in the field worker agenda and will inform about the visit (day/hour and the field worker name) and will check the participant's data (name, address, etc)

In case the participant don't want to participate in the study, he/she won't be substituted by another one.

In any case, the phone operator will try to make a fast questionnaire about COPD, asthma, smoke and chronic disease with all participants. You can find the *Questionnaire Quick Fast* in the annex 1.

In case the participant accepts to participate to the study the phone operator will provide him/her during the contact with the following information:

1. General information about the study,
2. Information about the consent form, (*Consent form: study on new methods to evaluate respiratory health in the community*) You will find this information sheet in the protocol or in the 2<sup>nd</sup> IMCA Group meeting dossier
3. Information about the questionnaire and the measurements. (*Information sheet about the questionnaire and other measurements to be performed in this study*) You will find this information sheet in the protocol or in the 2<sup>nd</sup> IMCA Group meeting dossier. The phone operator will schedule a visit with the field worker. At this moment the phone operator inform to the participant about the kind of visit, i.e. home visit or primary health care centre visit.

Then, two things can happen:

- a. The participant doesn't want to participate:
  - i. The phone operator ask to the participant about a brief questionnaire (12 general questions about COPD & asthma)
- b. The participant wants to participate:
  - i. The phone operator ask to the participant about a brief questionnaire (12 general questions about COPD & asthma)
  - ii. The phone operator will schedule a visit in the field worker agenda and will inform about the visit (day/ hour and the field worker name)
    - i. The phone operator will check the participant's data (name, address, etc)

We developed a parallel support application for the phone operator work. The tool help to the phone operators to organize the field work and to follow the evolution of the phone calls.

**Note:** Remember that you need a participants list additional for those participants that they don't want to participate.

### **7.3. HES Feasibility Study – (QQF): Adult’s questionnaire**

**IMCA II  
HES Feasibility Study – (QQF)  
(Questionnaire Quick Fast)  
Adult’s questionnaire**

**TO ANSWER THE QUESTIONS PLEASE CHOOSE THE APPROPRIATE BOX  
IF YOU ARE UNSURE OF THE ANSWER PLEASE CHOOSE 'NO'**

What is your date of birth?  
Are you male or female?

1. Have you ever been diagnosed of chronic bronchitis, emphysema or COPD?
2. Has your Doctor ever told you that you have had asthma?
3. Do you usually cough when you wake up?
4. Do you bring up phlegm from your chest to wake up?
5. Have you ever had wheezing or whistling in your chest?
6. Have you ever had any other lung disease?  
If Yes, which one?
7. Have you ever had a heart disease?  
If Yes, which one?
8. Have you ever had any other chronic disease  
If Yes, which one?
9. Do you usually smoke?  
If Yes, when did you started?

**THANK YOU FOR YOUR HELP!**

## 7.4. Access data base; Support Application for the phone operator

The application offers data in relation to:

1. Personal and administrative information.
2. Notes from the phone operators and the field workers
3. The exclusion criteria: **exitus**, home visit, invalidating disease,
4. And the monitoring of the interviews.

In the top you can find the administrative participant data.

On the right side you can see the comments and notes from the phone operators and the field workers and the exclusion criteria: **exitus**, home visit, invalidating disease.

On the left side you can see a folder with general information, the consent form, the brief questionnaire and the call history

### 7.4.1. General information folder

**In general information folder, you can find:**

1. Type of visit: home visit or primary health care centre
2. Accept/Refuse brief questionnaire
3. Did the participant receive the information about the study at home?

The screenshot shows the 'Indicators for Monitoring COPD and Asthma in the EU' web application. The interface is divided into several sections:

- Header:** IMCA logo and the title 'Indicators for Monitoring COPD and Asthma in the EU'.
- Participant Information:** Fields for Participant code (123456), Name (Carlos), Surname 1 (Martinez), and Surname 2.
- Personal Identifier Code:** Field for abcd123456789.
- Address Information:** Fields for Street (Street), Street name (Balmes), Street n° (123), Flat (1), City (Barcelona), Codigo Postal (8080), Pais (Spain), and Identificator code 2 (120).
- Phone Information:** Fields for Phone number 1 (123456789) and Phone number 2 (123456789).
- General Information:** A tabbed interface with 'General' selected. It includes a dropdown for 'Kind of interview' (Centro de Salud), and checkboxes for 'Participant don't want...?', 'Está pendiente para citar?' (checked), and '¿Ha recibido información/carta?'.
- Comments and Notes:** Sections for 'Comments Phone Operator' (Phone number 1 wrong, Dificult to find), 'Phone Operator notes', 'Comments Field Worker' (Address wrong, Interview without problems), and 'Field Worker notes'.
- Exclusion Criteria:** A dropdown menu.
- Monitoring of the visits:** A section for tracking interview progress.

## 7.4.2. Consent form

In the consent form folder, you can find a check list with the general study information, the consent form and the study measurements. The phone operator check the state of this patient decisions, i.e; you can see in this part that the participant received the general study information, he/she signed the consent form, he/she wanted to realize all the measurement except the blood sample.

**Indicators for Monitoring COPD and Asthma in the EU**

**Participant code** 123456 **Personal Identifier Code** abcd123456789

**Name** Carlos **Street** Street **Street name** Balmes **Street n°** 123 **Flat** 1

**Surname 1** Martinez **City** Barcelona **Codigo Postal** 8080 **Pais** Spain **Identifier code 2** 120

**Surname 2** **Phone number 1** 123456789 **Phone number 2** 123456789

General **Consent form** Fast Questionnaire Call evolution

- General study information?
- Consent form information?
- Sensor TA?
- Sensor weight?
- Sensor Sat O2?
- ¿Sensor spirometrie?
- Hight?
- Blood sample?

**Comments Phone Operator**  
Phone number 1 wrong  
Dificult to find

**Phone Operator notes**

**Comments Field Worker**  
Address wrong  
Interview without problems

**Field Worker notes**

**Exclusión Criterias** [dropdown menu]

**Monitoring of the visits**

### 7.4.3. Fast questionnaire

The fast questionnaire folder contains a group of twelve questions about COPD, asthma, smoke and co morbidities that the phone operator will complete in the first contact with the participant. The phone operator will can choose the answer of the question between a combo box of possibilities: yes, no or don't know.

**Indicators for Monitoring COPD and Asthma in the EU**

**Participant code** 123456 **Personal Identifier Code** abcd123456789

**Name** Carlos **Street** Street **Street name** Balmes **Street nº** 123 **Flat** 1

**Surname 1** Martinez **City** Barcelona **Codigo Postal** 8080 **Pais** Spain **Identificator code 2** 120

**Surname 2** **Phone number 1** 123456789 **Phone number 2** 123456789

**General** **Consent form** **Fast Questionnaire** **Call evolution**

**Género** Hombre

**Diagnosticado de bronquitis crónica, enfisema o EPOC?** No

**El médico le ha dicho si tiene asma?** NS/NC

**Tose habitualmente al levantarse?** Si

**Echa habitualmente esputo al levantarse?** No

**Se queda sin aliento al subir un piso a paso normal?** NS/NC

**Ha notado alguna vez silbidos en el pecho?** Si

**Se ha levantado alguna vez con opresión en pecho?** No

**Ha padecido o padece alguna enfermedad pulmonar?** Si

**Cuál?** COPD

**Ha padecido o padece alguna enfermedad corazón?** NS/NC

**Cuál?**

**Ha padecido o padece alguna enfermedad crónica?** No

**Cuál?**

**Fuma actualmente?** No

**Ha fumado?** Si

**Comments Phone Operator**  
Phone number 1 wrong  
Difficult to find

**Phone Operator notes**

**Comments Field Worker**  
Address wrong  
Interview without problems

**Field Worker notes**

**Exclusión Criteria**

**Monitoring of the visits**

#### 7.4.4. Call evolution

The call history folder is used by the phone operator to coordinate the phone calls and follow the status of the calls.

The evolution field is a drop down box with different options:

1. contacted,
2. contacted and excluded,
3. contacted and invited,
4. left a message (answer machine),
5. does not answer the phone.

The screenshot displays the 'Indicators for Monitoring COPD and Asthma in the EU' web application. The interface includes a header with the IMCA logo and title. Below the header, there are several form fields for participant information:

- Participant code:** 123456
- Personal Identifier Code:** abcd123456789
- Name:** Carlos
- Surname 1:** Martinez
- Surname 2:** (empty)
- Street:** Street (dropdown), **Street name:** Balmes, **Street n#:** 123, **Flat:** 1
- City:** Barcelona, **Codigo Postal:** 8080, **Pais:** Spain, **Identificator code 2:** 120
- Phone number 1:** 123456789, **Phone number 2:** 123456789

The main content area is divided into two sections:

- Call evolution:** A table showing the participant's call history over time. The table has columns for Day, Time, and Evolution. The data is as follows:

Day	Time	Evolution
Day1	1/02/2008	Time1 1245 Evolution1 No contesta
Day2	3/02/2008	Time2 1400 Evolution2 No contesta
Day3	5/02/2008	Time3 1835 Evolution3 Contestador
Day4	9/02/2008	Time4 900 Evolution4 No contesta
Day5	0/02/2008	Time5 2000 Evolution5 Contestador
Day6	2/02/2008	Time6 800 Evolution6 No contesta
Day7	5/02/2008	Time7 2100 Evolution7 Contactado y cit
Day8		Time8 Evolution8
- Comments and Notes:** Several text areas for recording information:
  - Comments Phone Operator:** Phone number 1 wrong, Dificult to find
  - Phone Operator notes:** (empty)
  - Comments Field Worker:** Address wrong, Interview without problems
  - Field Worker notes:** (empty)
  - Exclusión Criteria:** (dropdown menu)
  - Monitoring of the visits:** (empty)

At the bottom of the 'Call evolution' section, there is a navigation bar with 'Record: 1 of 1', 'No Filter', and a search field.

## **8. Tasks and role of the field worker/s**

## 8.1. The interviews protocol

The visit make take place in the Primary Health Care Centre or in the participant's home. One day before the visit, the field worker will contact with the participant to confirm the visit. The day of the visit, the field worker has already the agenda synchronized with all the visits for the day.

The first step to follow in a interview is to inform about the study, the questionnaire and measurements and to sign the consent form with the activities that the participant wants to participate.

We suggest every participant sign the consent form previously to start with the interview. (*Consent form: study on new methods to evaluate respiratory health in the community*) You will find this document in the protocol or in the 2<sup>nd</sup> IMCA Group meeting dossier.



The second step is to realize the biomedical measurements (blood pressure, oxygen saturation, weight, height, spirometry and blood sample). You can find the standards and recommendations for the different sensors in the document: "*Fieldwork Equipment in the IMCA II project*"

The third step is to complete the questionnaire (Adults questionnaire or Children questionnaire).

The fourth step is the post bronchodilator spirometry.