EpiReumaPt: how to perform a national population based study – a practical guide

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ACTA REUMATOL PORT. 2015;40:128-136

ABSTRACT

Background: The aim of this article was to describe and discuss several strategies and standard operating procedures undertaken in the EpiReumaPt study – which was the first Portuguese, national, cross-sectional population-based study of Rheumatic and Musculoskeletal Diseases (RMD).

Methods: The technical procedures, legal issues, management and practical questions were studied, analyzed and discussed with relevant stakeholders. During the 1st phase of EpiReumaPt the coordination team and Centro de Estudos de Sondagens e Opinião (CESOP) worked to recruit and interview 10,661 subjects. The 2nd phase involved the participation of a multidisciplinary team, several local authorities, a specialized vehicle ("mobile unit") and a specific software program for the clinical appointments. The development of specific recruitment strategies improved the participation rate. Blood samples were collected and sent to Biobanco-IMM and to a central lab for immediate measurements. In the 3rd phase the RMD diagnosis were validated by a team of three experienced rheumatologists - clinical data, imaging and lab test results were revised according to previously published classification criteria.

Conclusion: EpiReumaPt was a nationwide project successfully conducted, which followed critical logistic/coordination and research strategies. EpiReumaPt methodology and coordination could be used as an example for other epidemiologic endeavors and public health policies.

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Keywords: Epidemiologic studies; Population-based study; Rheumatic Diseases; Epidemiology; Cross-sectional study; Study management

INTRODUCTION

Large-scale observational epidemiologic studies are scarce in Portugal. The Portuguese Epidemiologic Study of Rheumatic Diseases (EpiReumaPt) was a challenging project, as the first national, cross-sectional, population-based study of Rheumatic and Musculoskeletal Diseases (RMDs). The EpiReumaPt study had a pioneering design in Portugal. The protocol was developed after reviewing other international studies and adapted to the Portuguese context[1-5]. The EpiReumaPt protocol was published before the work field. EpiReumaPt covered mainland Portugal, *Região Autónoma dos Açores* (Azores) and *Região Autónoma da Madeira* (Madeira). The technical procedures, legal issues, management and practical questions were studied, analyzed and discussed with all relevant stakeholders, Authorities and partners who contributed to the EpiReumaPt project.

The aim of this article is to describe and discuss all standard operating procedures, strategies and challenges related to the development of the Portuguese large-scale epidemiologic study, EpiReumaPt. An article focusing on the EpiReumaPt methodology (rather than management issues) is also published in this issue of Acta Reumatológica Portuguesa: *EpiReumaPT-the study of Rheumatic and Musculoskeletal diseases in Portugal: a detailed view of the methodology.*

EPIREUMAPT: CONCEPT AND CONTEXT

The prevalence of Portuguese RMDs was poorly defined. The National Program Against Rheumatic Diseases (2004-2014), promoted by the Directorate-General of Health and part of the National Health Plan for 2004/2010, aimed to promote a comprehensive and articulated approach of health services, in order to reduce the risk of developing RMDs among the Portuguese population, and to provide suitable treatment and rehabilitation for those with RMDs[7]. One of the specific goals was to determine the prevalence of the RMDs covered by the Program: hand, knee and hip osteoarthritis (OA), low back pain (LBP), rheumatoid arthritis (RA), fibromyalgia (FM), gout, spondyloarthritis (SpA), periarticular disease (PD), systemic lupus erythematosus (SLE), polymyalgia rheumatica (PMR) and osteoporosis (OP)[7]. EpiReumaPt was the first large-scale project studying RMDs in the Portuguese population, designed to achieve this specific goal. It also aimed to assess the impact of RMDs in relation to quality of life, function, use of healthcare resources and work participation[6]. The main promotor of EpiReumaPt was the Portuguese Society of Rheumatology (SPR). This project was also supported by the Directorate-General of Health and Nova Medical School (NOVA University of Lisbon) in collaboration with the Portuguese Catholic University.

FUNDING, INSTITUTIONAL AND SCIENTIFIC SUPPORT

The first steps to develop EpiReumaPt began in 2005 after the National Program Against Rheumatic Diseases was published. In October 2010 EpiReumaPt was awarded with a Directorate-General of Health competitive award. This was the key funding to start the working process. EpiReumaPt was budgeted in 1.5 million euros and in addition to the primary grant from the Directorate-General of Health (which covered 50% of the estimated cost) it was necessary to find other sponsors. Unrestricted grants were awarded by the following entities or companies: Calouste Gulbenkian Foundation, Pfizer, Merck Sharp & Dohme, Abbvie, Roche, Bial, Servier, Astra Zeneca Foundation, as well as individual support by some rheumatologists. Other institutions supported the study by providing goods or lowering the prices of services and products (*Galp Energia, Germano de Sousa-Centro de Medicina Laboratorial, Açoreana Seguros, HappyBrands, Clínica Médica da Praia, CAL-Clínica*). Scientific endorsement was given by the promoters and by three other Portuguese Medical Schools: *Faculdade de Medicina da Universidade de Lisboa* (Lisbon, Portugal), *Faculdade de Medicina da Universidade do Porto* (Porto, Portugal) and *Faculdade de Medicina da Universidade de Coimbra* (Coimbra, Portugal). Institutional endorsement was given by the President of the Portuguese Republic (*Alto Patrocínio da Presidência da República*), by the Regional Government of Azores, by the Regional Government of Madeira, and by the Regional Health Administrations of *Norte, Centro, Alentejo, Algarve,* and *Lisboa e Vale do Tejo*. Other institutions and national associations also gave their endorsement (*Centro Hospitalar do Médio Tejo, Hospital de S. João, Câmara Municipal de Lisboa*, *Associação Nacional de Freguesias)*. Patient Associations with RMDs were also included as social partners.

RESEARCH TEAM

The EpiReumaPt study protocol was developed by the

core research team and was published in the end of 2010[6]. Later when EpiReumaPt was awarded the grant from the Directorate-General of Health, other investigators joined the research team. The Coordination Team, including the Principal Investigator, the Co-Principal Investigator and the Study Manager, was established in March 2011. This small Coordination Team was responsible for the executive, financial and logistical decisions, and held weekly meetings since March 2011. National and international experts were invited as external advisors, especially in the area of epidemiology.

STUDY DESIGN AND METHODOLOGY

EpiReumaPt was an epidemiologic, observational and cross-sectional population-based study. The recruitment took place from the 19th September 2011 to the 20th December 2013, and involved a three-stage approach (Figure 1)[8]. The 1st phase (RMD screening) started with a face-to-face interview performed at subjects' households, which were selected by a random route methodology[6,8]. In the 2nd phase (RMD diagnosis) all subjects who screened positive for at least one RMD during the 1st phase, and also a random 20% sample of individuals without positive screening for rheumatic complaints, were invited to be observed by a rheumatologist. Finally, in the 3rd phase, RMD diagnoses were validated after revision of the clinical data by a team of three experienced rheumatologists.

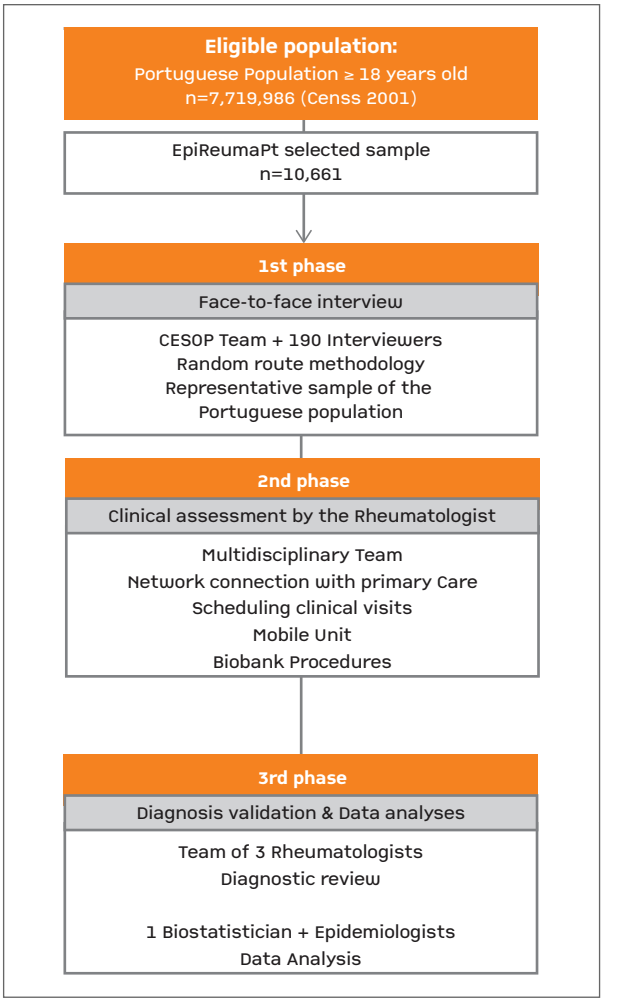

FIGURE 1. EpiReumaPt study design
CESOP: Centro de Estudos e Sondagens de Opinião da Universidade Católica Portuguesa

PLANNING AND DEVELOPMENT OF THE 1ST PHASE OF THE STUDY: FACE TO FACE INTERVIEW

The 1st phase of EpiReumaPt was performed with the collaboration of the expert national center in large-scale population studies located in the Catholic Portuguese University - *Centro de Estudos e Sondagens de Opinião* (CESOP). The CESOP team had a coordination board that was responsible for organizing the field-work and three sub-coordinators that were responsible for organizing the data collection of the 1st study phase.

The team that conducted the 1st phase survey was composed by 190 interviewers, non-physicians, who were recruited by the CESOP coordination board through a selection process composed of 2 stages: interview selection plus a theoretical and practical training session. This training session included topics related to: study design, study features, logistics, clinical issues related with RMDs, ethical and legal issues, random-route methodology (sample selection), interview procedures (roll-play exercises), survey and software training. Only the candidates that successfully went through the two phases were selected.

Afterwards, the team of 190 interviewers was divided into five teams (10-15 elements per team) who worked across the country during the recruitment period: Lisbon team (responsible for the recruitment in Lisbon & *Setúbal, Alentejo, Algarve, Estremadura, Ribatejo and Beira Baixa*), Coimbra team (responsible for the recruitment in *Beira Alta and Beira Litoral*), Porto team (responsible for the recruitment in *Douro Litoral, Minho, Trás-os–Montes & Alto Douro*), Azores

FIGURE 2. Portugal regions

team and Madeira team (Figure 2).

The 1st phase face to face interview was conducted with the Computer Assisted Personal Interview (CAPI) system: all interviewers had a computer with the software which provided the questionnaire applied to all subjects. The questionnaire was designed by the EpiReumaPt research team to screen for RMDs and included questions on specific rheumatic symptoms and an algorithm to screen for each RMD (OA, LBP, RA, FM, gout, SpA, PD, SLE and PMR). During the interview, subjects were also asked about socio-demographic and socio-economic factors, lifestyle, health care resources consumption, work status, functional status, quality of life, mental health status and comorbidities[6] (Figure 3). Both the survey and software performance were tested in a pilot sample of patients and healthy controls, and results validated by the EpiReumaPt research team before being used by the interviewers.

Each interviewers team worked daily on the field (week and weekend) in groups of 4/5 elements, and covering a different route. When no subject was found in a first visit of the selected household, he/she could not be replaced, unless that household had been visited in three different times, including evenings and weekends. The most successful schedules were in the evenings and weekends. Quality control of the interviews was made by the team Coordinators of CESOP, by randomized phone calls among the recruited subjects.

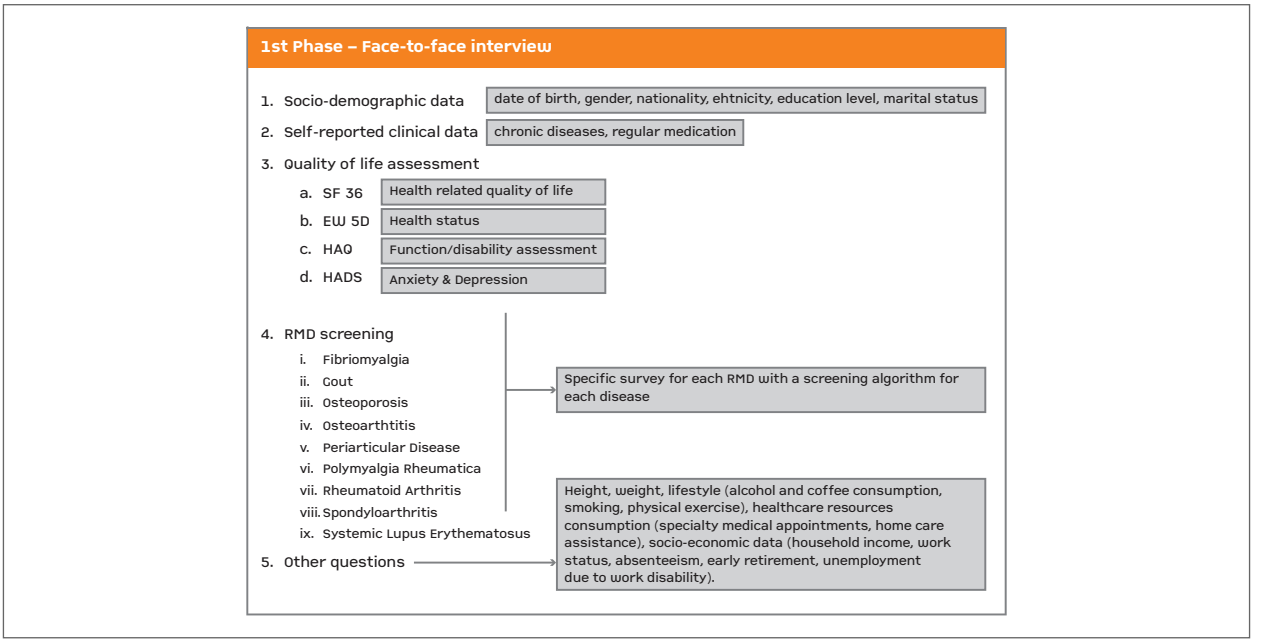

FIGURE 3. Phase 1 survey
SF36 – short form (36) form health survey; EQ5D – European Quality of life Questionnaire; HAQ – Health Assessment Questionnaire; HADS – Hospital Anxiety and depression scale

PLANNING AND DEVELOPMENT OF THE 2ND STUDY PHASE: CLINICAL ASSESSMENT BY A RHEUMATOLOGIST

IDENTIFICATION OF PRIMARY CARE CENTERS FOR CLINICAL VISITS

The 2nd phase clinical visits were performed at the Primary Care Centers of the participant's area of residence. In each region, the EpiReumaPt Coordination Team identified the Primary Care Centers, taking into account the localities where subjects were recruited. All Primary Care Centers were contacted in order to plan and schedule the days of clinical visits and to ensure that all needs were fulfilled: 1 or 2 rooms for clinical visits and an electricity source for the mobile unit. In Azores and Madeira Islands an extra consultation office was required to collect blood samples and to perform the peripheral dual energy X-ray absorptiometry (since the mobile unit was not available). All Regional Health Administrations (*Lisboa e Vale do Tejo, Alentejo, Algarve, Centro, Norte,* Regional Governments of Azores and Madeira) were previously contacted and committed to liaise with all Primary Care Centers.

SCHEDULING VISITS FOR THE 2ND PHASE

As mentioned before, CESOP interviewers identified, through the RMD screening survey, the subjects that were selected for the 2nd phase. This information was weekly sent by the CESOP Staff Coordinator to the Coordination Team of EpiReumaPt. All the identified subjects were contacted by telephone to be scheduled for the observation by the rheumatologist. The time between the CESOP interview and the clinical visit was less than 1 month.

Clinical visits were usually scheduled twice a week, but sometimes it was necessary to schedule more days. For instance, in some areas (*Trás-os-Montes,* Azores - *S. Miguel, Terceira and Faial Islands, and* Madeira Island), clinical visits were scheduled during the entire week in order to optimize journeys of the research team.

CLINICAL ASSESSMENT PERFORMED BY A MULTIDISCIPLINARY TEAM

A multidisciplinary team with rheumatologists, radiology technician, a nurse and a staff coordinator (in the Mainland Portugal also the driver of the mobile unit was included in the team) performed or assisted the clinical visits across the country. The EpiReumaPt Coordination Team was responsible for assembling this team and planning their work every week, according to their area of residence and availability. This strategy required a pool of 7 nurses, 3 radiology technicians, 5 drivers and 3 staff coordinators, and 95 experienced rheumatologists (EpiReumaPt study group), who graciously and voluntarily accepted to participate in the study. To promote the crucial participation of rheumatologists in this global effort, local rheumatology teams were invited according to the region recruited. Monthly newsletters and letters with the EpiReumaPt schedule were also sent. Rheumatologists of the research team were also scheduled - they were responsible by almost half (47%) of the total number of clinical visits.

To standardize the clinical assessment procedures a training handbook/protocol was provided to all rheumatologists and other clinical assistants (nurses and radiology technicians). Moreover, the staff coordinator provided a short summary of all study procedures and supported the rheumatologists with information and details regarding the software for data collection and the logistical issues in every clinical appointment journey.

The interviews and subsequent examinations followed a standard protocol that included: clinical history, physical examination, guidance about imaging and laboratory investigations (if necessary) and written informed consent. Computed assisted software specifically designed for the study was used to support the management of clinical visits and data collection during the 2nd phase. After the rheumatologist collected the clinical history and decided the differential diagnosis, the hypothetical RMD were selected in the software and specific questions related to validated classification criteria had to be answered. This software was tested and validated by the research team prior to the beginning of the study.

Finally, appropriate laboratory or imaging investigations were requested in order to achieve a definitive diagnosis. In Mainland Portugal, imaging investigations were performed at the mobile unit that supported all clinical visits (see below). In Azores and Madeira, the support of local hospitals or clinics was required to provide these tests.

The rheumatologist also invited all the subjects to sign 2 additional informed consents: to store blood samples in a biobank and to participate in the Portuguese Cohort Study of Rheumatic Diseases[9].

MOBILE UNIT TO SUPPORT THE CLINICAL ASSESSMENT

A mobile unit (adapted vehicle) was built and fully

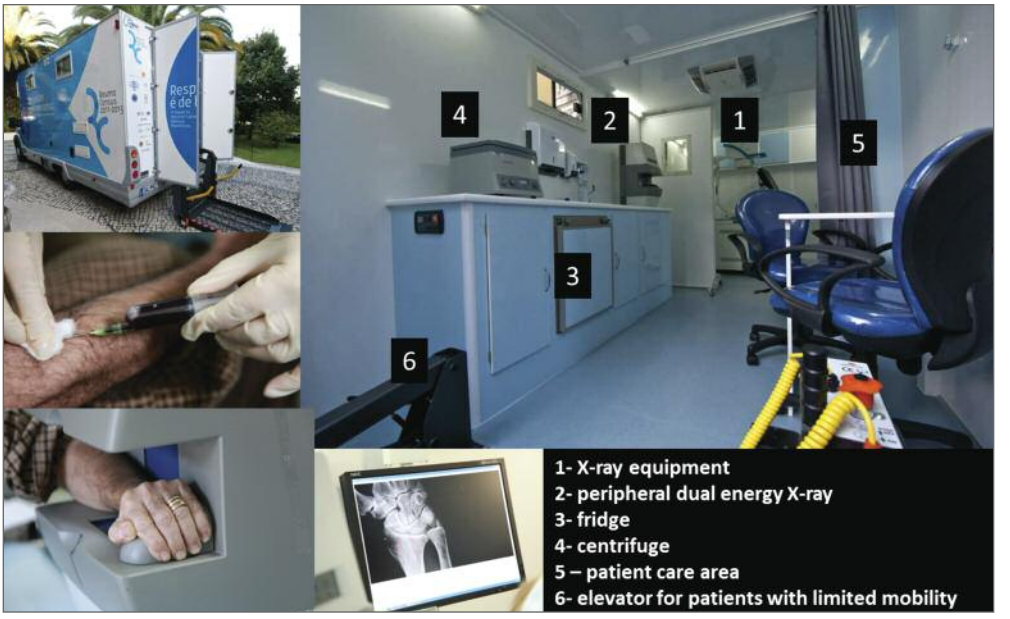

FIGURE 4. Mobile Unit

equipped as required (Figure 4) before the start of the study and was equipped to assist the clinical assessment by the rheumatologist, enabling him to perform the required imaging and laboratory tests: X-ray of the affected body segments, peripheral dual energy X-ray absorptiometry and blood collection.

BIOBANK PROCEDURES

Guidelines for the collection, identification and transport of samples to the biobank were provided to standardize sample collection as well as the identification of samples and transportation procedures. The nurse drew the blood samples in the mobile unit just after the clinical visit with the rheumatologist; serum was separated by centrifuging at the screening site and immediately placed in a refrigerator. On the same day, or within two days, the samples were sent in a cooler to a central diagnostic laboratory in Lisbon, transported by a dedicated company. Serum analyses were performed in fresh blood samples, and the remaining serum and clot stored in the biobank at *Instituto de Medicina Molecular* (Biobanco-IMM).

3RD PHASE - DIAGNOSIS VALIDATION & DATA ANALYSES: PLANNING AND WORK FIELD

In order to refine and validate the 2nd phase diagnostic decisions, a team of three rheumatologists reviewed all the clinical data from each participant, including the imaging and laboratorial test results. A specific protocol was developed to support this task.

The 3rd phase was developed during the 1st semester of 2014[8] and after this, the clinical database was cleaned and merged with the 1st phase database to provide a single EpiReumaPt database. A multidisciplinary team including a biostatistician and epidemiologists was set-up to perform data cleaning and support data analyses.

STUDY AWARENESS AMONG THE PORTUGUESE POPULATION

In Portugal, large-scale epidemiological studies are not common. At the beginning of EpiReumaPt the project was advertised among the Portuguese population, clarifying certain aspects:

1. The study did not aim to screen all the "Portuguese population" for RMDs, but selected random subjects.
2. The ultimate goal of this kind of study was the general public health, rather than any individual or institutional benefits.

To improve the recruitment rate other aspects had to be taken into account:

Lack of confidence and uncertainties among certain population subgroups (eg. the elderly population) –

strategic partnerships were established, namely with the National Association of Local Councils, to promote and disseminate EpiReumaPt among the population. We also liaised with the police and other public security authorities, with the Church, and with the local councils and other local authorities, to explain the study's methodology (especially the phase 1 interview) in order to gain the trust of the population improving its compliance.

The relative lack of availability of the active population to participate in the study (especially in larger cities), led CESOP to plan the work field during the weekends, during the week and during the evenings. A promotional event of EpiReumaPt with a press release was held on 9th September'2011, before starting recruitment. A website was also developed and updated throughout the EpiReumaPt recruitment (http://www.reumacensus.org/)[10] as well as a monthly newsletter that was sent to a large mailing list, which included national and local authorities (health and social authorities), media, sponsors, rheumatologists and other health care professionals, among others.

DATA PROTECTION AND ETHICS

EpiReumaPt was performed according to the principles established by the Declaration of Helsinki, revised in 2013 in Fortaleza (Brazil)[11] and according to the Portuguese law at the time the study begun (Law n. 46/2004, of 24th August). As an observational study it was reviewed and approved by competent Portuguese authorities: NOVA Medical School Ethics Committee and National Committee for Data Protection. The study was also reviewed and approved by the Ethical Committees of Regional Health Authorities. In addition to the Declaration of Helsinki, EpiReumaPt complied with the following laws and standards: Protection of Personal Information (Law n.67/98 of 26th of October[12] and CNPD deliberation n.227/2007[13]); and Genetic, clinical and health personal information (Law n.12/2005, of 26th January[14]).

Data protection was assured by data encryption according to the Portuguese law and according to CNPD deliberation n.227/2007[14] (processing of personal data carried out under scientific clinical research). The data encryption process kept the confidentiality and anonymity of each subject: in the 1st phase, subjects were identified with a unique code (ID) that was anonymous (each subject had an ID which was the same throughout the study procedures); in the 2nd phase, personal data (ID, name, address and contact details) were only available to the rheumatologist and Technical Team (nurse and radiology technician). Data collected in both phases (1st and 2nd) were exported to a single database. Decryption was only possible with a secure password only known by the Principal Investigator. All the computers that were used during the study procedures (1st phase, 2nd phase and also 3rd phase) had restricted access with a password.

Also Biobanco-IMM samples were provided according to the Portuguese law that assures data protection of genetic information and health clinical data (Law n.67/98 of 26th of October). Blood samples were collected and coded with the subject ID. Personal data were not visible or available to professionals involved in the circuit of the blood sample (from sample collection to the storage in the Biobanco-IMM). Only the PI had access to the code allowing access to the personal, clinical and biologic data of each subject.

INFORMED CONSENT

Informed consent for the EpiReumaPt study was mandatory and collected by interviewers in the 1st phase. Additional consents for Biobanco-IMM and Cohort study were also mandatory and collected by the rheumatologist during the 2nd phase (Figure 5). Subjects not invited for observation in the 2nd phase signed the informed consent to participate in the cohort study already in 1st phase. All subjects received clear information in lay terms about the research being undertaken (verbal information and a specific leaflet – main study, cohort study and Biobanco-IMM), and they were given the opportunity to ask questions and enough time to decide whether to participate in the study. Subjects were only asked to sign the consent form after the research team was assured that the patient had fully understood the study objectives and procedures. For each signed consent form, one copy was given to the participant while the other copy was archived by the site coordinator.

DISCUSSION

EpiReumaPt was a complex large-scale project with several management challenges. Strategies had to be defined and operating procedures regarding logistic, financial and coordination-related issues had to be implemented. Previously published strategies were con-

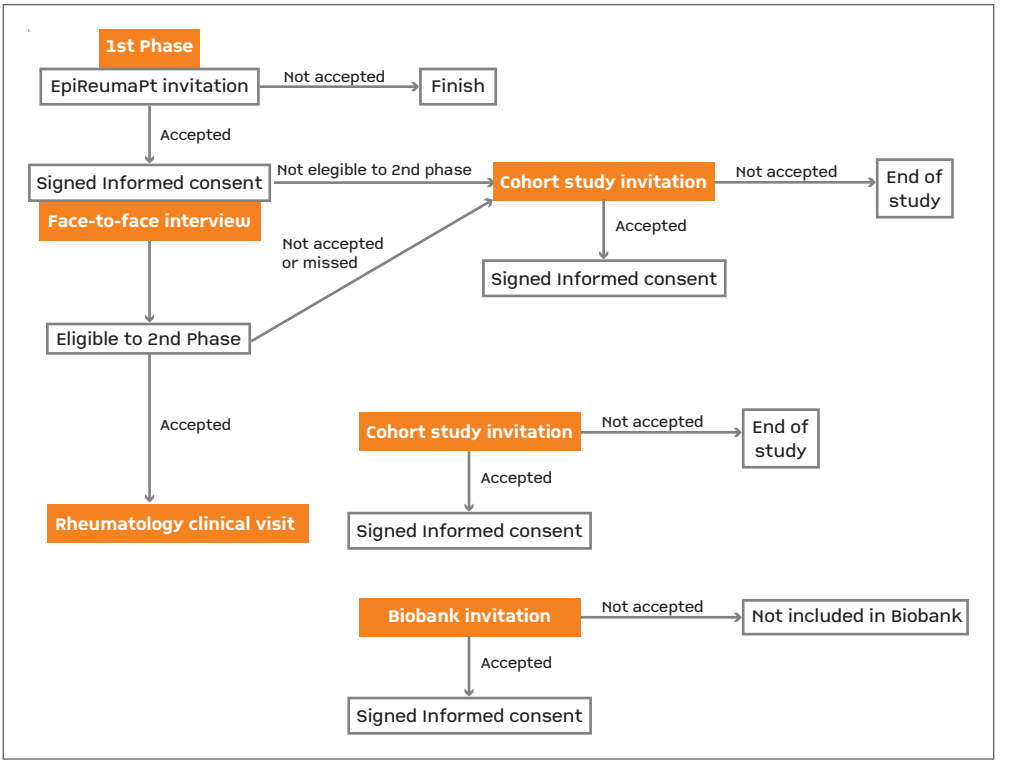

FIGURE 5. Informed consent flowchart

sidered insufficient to secure a good recruitment rate and several Country-specific actions were taken. The efforts to increase subjects' compliance were successful, particularly the measures related to raising study awareness among the general population (partnership with local authorities, the police and Church members), and to the schedule adjustment of interviews and clinical visits to the weekends and evenings. Also, Primary Care Centers were chosen as close as possible to the subjects' households.

Regarding management issues, the coordination of a multidisciplinary team over 27 months of work field, was a challenge. The very successful work field was only possible thanks to dedicated team members that gave response to all issues and unexpected situations that arose. In this context, also rheumatologists' commitment was determinant to the success of the project. The involvement of the local teams was a good strategy to maintain the work progress in the field and the existence of a core medical team of EpiReumaPt was crucial to be able to fulfill the planned schedule with no productivity losses.

Another main challenge was also the management of blood samples transportation to the Biobanco-IMM and to the central laboratories (both located in Lisbon), especially in the regions far from Lisbon. An accurate coordination between teams was necessary, as well as with the transportation company to ensure the quality of the samples. This issue was even more important in Azores and Madeira because it was necessary to coordinate all the previous factors with flights schedules.

In conclusion, as a result of detailed planning and standard operating procedures, EpiReumaPt was a nationwide project successfully conducted, which followed critical logistic/coordination and research strategies. EpiReumaPt methodology and coordination could be used as an example for other epidemiologic endeavors and public health policies.

ACKNOWLEDGEMENTS

The EpiReumaPt Study Group would like to acknowledge the invaluable help of external consultants: João Eurico da Fonseca, MD PhD, Loreto Carmona, MD PhD, Henrique de Barros, MD PhD, José António Pereira da Silva, MD PhD. DGS: Francisco George, MD. *Faculdade de Medicina da Universidade de Coimbra, Faculdade de Medicina da Universidade de Lisboa, Faculdade de Medicina da Universidade de Porto*, Biobanco-IMM, Regional Government of Azores, Regional Government of Madeira, Regional Health Administrations of *Norte, Centro, Alentejo, Algarve,* and *Lisboa e Vale do Tejo*, *Centro Hospitalar*

do Médio Tejo, Hospital de S. João, Câmara Municipal de Lisboa, *Associação Nacional de Freguesias,* Patient Associations with RMDs.

UNRESTRICTED GRANTS

EpiReumaPt was endorsed by the Alto *Patrocínio da Presidência da República* and was supported by a Grant from Directorate-General of Health. The project was also sponsored by: Fundação Calouste Gulbenkian, Fundação Champalimaud, Fundação AstraZeneca, Abbvie, Merck Sharp & Dohme, Pfizer, Roche, Servier, Bial, D3A Medical Systems, Happybrands, *Centro de Medicina Laboratorial Germano de Sousa, Clínica Médica da Praia da Vitória, CAL-Clínica, Galp Energia, Açoreana Seguros* and individual support of rheumatologists.

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