



Aerobiological Information Systems and allergic respiratory disease management AIS LIFE (AIS LIFE LIFE13 ENV/IT/001107)

**Annual meeting
Vienna _ Austria
19-20 of June 2015**

Action progress of CNR Institute of Clinical Physiology within AIS-LIFE project

Sandra Baldacci

**Pulmonary Environmental Epidemiology Unit,
CNR Institute of Clinical Physiology, Pisa, Italy**



UNIVERSITÀ
DEGLI STUDI
FIRENZE

DISPAA
DIPARTIMENTO DI SCIENZE DELLE
PRODUZIONEI AGROALIMENTARI
E DELL'AMBIENTE



DIPARTIMENTO DI BIOLOGIA
UNIVERSITÀ DI PISA



ISTITUTO DI FISILOGIA CLINICA
CONSIGLIO NAZIONALE DELLE RICERCHE



MEDICAL
UNIVERSITY
OF VIENNA



IFC-CNR within AIS-LIFE project “Aerobiological Information Systems and allergic respiratory disease management” is involved in actions:

Implementation actions

- B1-** Implementation of IIS and PPI in three countries (enrolment, randomisation, educational intervention);
- B2** - Health assessment of Allergy Patients;

Monitoring of the impact of the project action

- C2** - Validation and comparison of the effectiveness of the two Aerobiological Information Systems;

Communication and dissemination actions

- D3** - Stakeholder Involvement Activities;
- D4** - Target Audience / General Public Awareness Raising;

Project management and monitoring of the project progress

- E1** - Overall project operation.

In particular , IFC-CNR is beneficiary responsible for implementation of **actions B1, B2 and C2.**



Expected activities

On the 12th month of activity, according to the protocol the following deliverables are expected considering Actions B1,B2 and C2 of which CNR is the Beneficiary responsible for implementation:

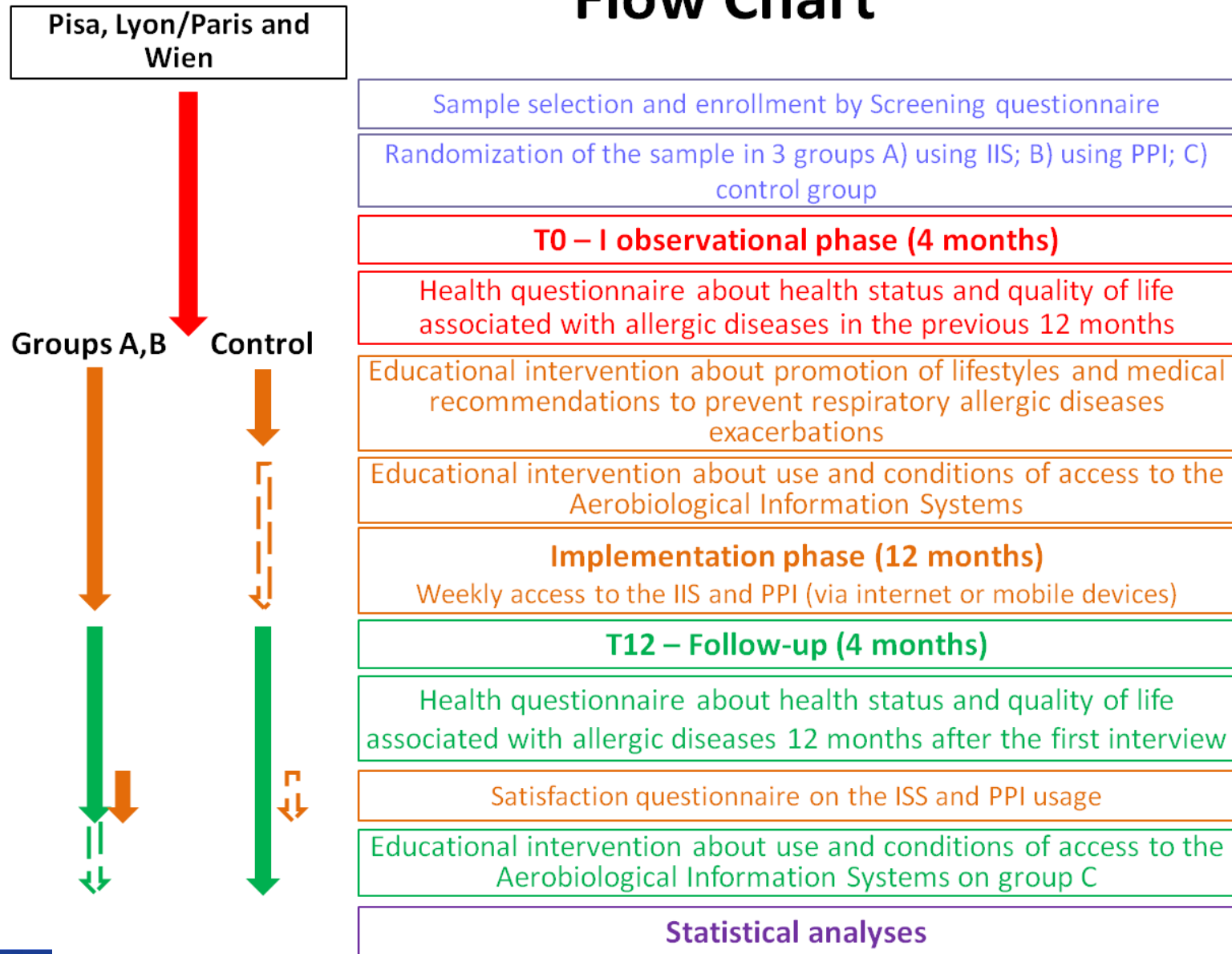
B1.1 - Detailed protocol of the field survey /educational material (Action: B1; deadline: 31/05/2015)

B2.1 - Daily diary, health and satisfaction questionnaires (Action: B2; deadline: 31/05/2015)

No deliverable associated to the action C2 is expected in the initial part of the project.



Flow Chart



Study Timetable

	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33	M34	M35	M36
SET-UP phase																																				
Enrollment, Screening questionnaire																																				
Health Q (T0), education groups A, B																																				
Implementation phase																																				
Data input																																				
Health Q (T12), education group C																																				
STATISTICAL ANALYSES																																				
REPORT WRITING																																				

Enrollment, randomization, first observational phase and educational intervention **from August to November 2015** by each partner involved in the field survey.



Eligible subjects in Italy, Austria and France

Country	Source	Eligible	Enrolled at Screening Q considering a loss of 30%	Enrolled at T0 (-30% loss)/Total expected
Italy	pre-existent databases	728* (390<65 yrs)	510 (273<65yrs)	357/250 (191/250)
	new enrollment	57**	40	28/250
France***	pulmonary clinics	177	124	87/250
Austria	???	???	???	???

*Considering subjects performing both PI2 and PI3

** Considering students registered to the Earth Sciences Department of Pisa University (2014-2015) and a 19% prevalence of pollinosis (from PI2 study)

***Considering newly recruited patients



Inclusion criteria

- Subjects suffering from pollen allergy and reporting seasonal symptoms (last 12 months).
- Subjects ≥ 18 years of either sex.
- Subjects spending most of the week (at least 5 days/week) living, studying, working in the 3 study areas of Pisa, Paris/Lyon and Wien.

The requirements for eligibility will be checked through the assessment of inclusion criteria as reported in the Screening questionnaire. Each subject willing to participate in the study should provide in advance their signed consent form.



Exclusion criteria

- Subjects not reporting seasonal symptoms (last 12 months).
- Subjects ever treated with allergen-specific immunotherapy (allergen-SIT) with pollen extracts.
- Subjects not spending the entire duration of the project (12 months) in the study area.
- Subjects not spending most of the week in the study area.
- Selected subjects that, for any reason, manifestly should not be able to collaborate in the study.
- Subjects < 18 years.



Research tools

The following diagnostic and monitoring tools will be utilized:

Screening questionnaire

- Telephonic Health questionnaire
- Daily Diary
- Satisfaction questionnaire



Steps from August to November 2015

ACTION B.1 and B.2

Enrollment: on the basis of preexistent archives (databases from previous studies, GPs or specialist patients databases etc.) and of new enrollment via web/media campaigns, eligible subjects will be contacted in order to provide them all the information about the study and to obtain the informed consent form.

Randomization: the selected subjects will be randomized into 3 groups: A) using the Integrated Information System (IIS); B) using the Personalized Pollen Information system (PPI); C) not exposed to any information system (controls).

First observational phase (T0): interview (by telephone, frontal interview on paper questionnaire or web questionnaire) to fill in the Health questionnaire about the health status and quality of life associated with allergic diseases in the previous 12 months (all the groups).

Educational intervention: educational intervention about use and conditions of access to one of the two AIS (groups A and B), promotion of lifestyles and medical recommendations to prevent exacerbations of respiratory allergic diseases (groups A, B and C).



Completed activities

- Field survey protocol (Italian and English versions), concerning the field study to assess efficacy of PPI and IIS systems, has been prepared as extended and shortened versions.
- Educational material is completed in Italian version.
- The Screening Questionnaire, the Health Questionnaire and the Satisfaction Questionnaire are completed in Italian and English versions according to pre-existing validated questionnaires and partner's revisions.
- A brief guide to the PPI and its mobile application is ready (Italian and English versions) and is circulating to partners for their revision.
- A dissemination letter for Italian stakeholders presenting the aims and the objectives of the AIS project has been prepared.
- A graphic / textual document has been prepared to be uploaded on the Pisa University website in order to launch and advocate AIS LIFE project at local level and, through a link to the official AIS LIFE web site, to enroll potential eligible users willing to participate in the field survey.



Furthermore, the realization of a centralized platform hosted by AIS web site to be utilized for enrollment, data collection, education, monitoring has been proposed to partners/coordinator. This system could be used by each partner involved in the field survey but also to coordinator for having a continuous update of the field survey.

A budget for the implementation and management of this online platform has been provided by Techno-science Unit, IFC, CNR to be compared and discussed in respect to other estimates.



Budget for the implementation and management of AIS online platform provided by Techno-science Unit, IFC, CNR

ACTION B.1 and B.2

Necessità/possibilità:	Costo stimato	Note
Gestione Server per centralizzazione e raccolta dati SQ e/o centralizzazione e raccolta dati HQ e/o sito disseminazione e/o moodle: - implementazione server virtuale (max 50GB archiviazione, 2GB RAM) - installazione e configurazione software: WebServer, LimeSurvey (questionari) e DB (Mysql o PostgreSQL) o altro (in base alle necessità); - backup dei dati/server; - gestione del domino (eventuale); - certificato per connessione cifrata verso il server; - gestione mailing list e/o dominio posta elettronica (eventuale).	2500,00 €	2000,00 € primo anno, 500,00 € successivo
Sviluppo Q screening online con responsiveness (fruibilità anche su smartphone/tablet)	2000,00 €	
Programma gestione e restituzione score online / generazione codice alfanumerico / assegnazione al gruppo di studio		incluso nella voce precedente
Sviluppo Q health online con responsiveness (fruibilità anche su smartphone/tablet)	3000 €	
Sviluppo moodle educativo, installazione, configurazione, preparazione del corso (NO gestione iscritti e contenuti corso)	2000,00 €	
Totale	9500,00 €	
Gestione sito (eventuale) disseminazione (comprende mantenimento server anche per 5 anni successivi alla chiusura del progetto, con backup del sito e meccanismi per inserire autonomamente tweet, news, foto)	10-12.000 €	



Aerobiological Information Systems and allergic respiratory disease management_AIS
(AIS LIFE LIFE13 ENV/IT/001107)

www.ais-life.eu



Pending actions/critical aspects

- As soon as possible the English version of educational material will be sent to the other partners in order to have their revisions.
- As soon as possible the partner have to review the brief guide to the PPI and its mobile application (sent to all the partners on 24/05/2015 asking their suggestions/modifications).
- Questionnaires and protocols have yet to be translated into French and German by partners.
- The realization of a centralized platform hosted by AIS web site to be utilized for enrollment, data collection, education, monitoring have to be confirmed (or rejected).
- Enrollment, randomization, first observational phase and educational intervention **from August to November 2015** by each partner involved in the field survey.



Financial reporting

Due to local administrative problems IFC-CNR has not yet uploaded on dropbox the following documents expected within June 5:

- financial reporting file updated to 30/04/2015;
- cost for action file updated to 30/04/2015;
- all the supporting documents related to the expenses made until 30/04/2015 according to Personnel and Travels.



***“Many thanks for the invitation
and for the attention”.***

Sandra Baldacci

