



FP7-ENV-2008-226873

<http://www.mbkds.net/>

D5.5 Interim summary of database completion status

WP5 – Data analysis and management

V2.0

Final

Lead beneficiary: CREAL

Date: 21/05/2013

Nature: Report

Dissemination level: PP

(Restricted to other programme participants (including the Commission Services))



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	Author(s): [REDACTED] (CREAL)	Version: v2.0 – Final	2/11

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Project URL	http://www.mbkds.net/		
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Definitions

- Partners of the MOBI-KIDS Consortium are referred to herein according to the following codes:
CREAL - Fundació Centre de Recerca en Epidemiologia Ambiental (Spain) – Coordinator
FIMIM - Fundació IMIM (Spain) – Beneficiary
UU - Universiteit Utrecht (Netherlands) – Beneficiary
FT - France Telecom SA (France) – Beneficiary
HPA - Health Protection Agency (United Kingdom) – Beneficiary
LMU - Ludwig-Maximilians-Universitaet Muenchen (Germany) – Beneficiary
MUV - Medizinische Universitaet Wien (Austria)
UNITO - Università degli Studi di Torino (Italy)
ARECEA - Association pour la Recherche Epidémiologique dans les Cancers de l’Enfant et de l’Adolescent (France)
UOA-SARG - National and Kapodistrian University of Athens (Greece)
GERTNER INSTITUTE - Gertner Institute for Epidemiology & Health Policy Research (Israel)
UOTTAWA - University of Ottawa (Canada)
MONASH - Monash University (Australia)
AUCKLANDUNI - The University of Auckland (New Zealand)
- **Grant Agreement:** The agreement signed between the beneficiaries and the European Commission for the undertaking of the MOBI-KIDS project (ENV-226873).
- **Project:** The sum of all activities carried out in the framework of the Grant Agreement.
- **Work plan:** Schedule of tasks, deliverables, efforts, dates and responsibilities corresponding to the work to be carried out, as specified in Annex I to the Grant Agreement.
- **Consortium:** The MOBI-KIDS Consortium, conformed by the above-mentioned legal entities.
- **Consortium Agreement:** Agreement concluded amongst MOBI-KIDS participants for the implementation of the Grant Agreement. Such an agreement shall not affect the parties’ obligations to the Community and/or to one another arising from the Grant Agreement.
- **Deliverable review:** An evaluation procedure by one or more reviewers, which precedes the distribution of a deliverable (as defined in the Work plan) to the European Commission.
- **Quality assurance:** All the planned and systematic activities implemented to provide adequate confidence that an entity will fulfil requirements for quality.
- **Quality policy:** A set of principles on which quality assurance procedures are based.
- **Risk:** Uncertainty that may have a significant impact on the execution or outcome of the project, and which effect may be negative – a *threat* risk - or positive – an *opportunity* risk.
- **Foreground:** Means the results, including information, whether or not they can be protected, which are generated by activities in the Project. Such results include rights related to copyright; design rights; patent rights; plant variety rights or similar forms of protection.
- **Background:** Means information which is held by participants prior to their accession to the Grant Agreement, as well as copyrights or other intellectual property rights pertaining to such information, the application for which has been filed before their accession to the Grant Agreement, and which is needed for carrying out the indirect action or for using the results of the indirect action.

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1. INTRODUCTION

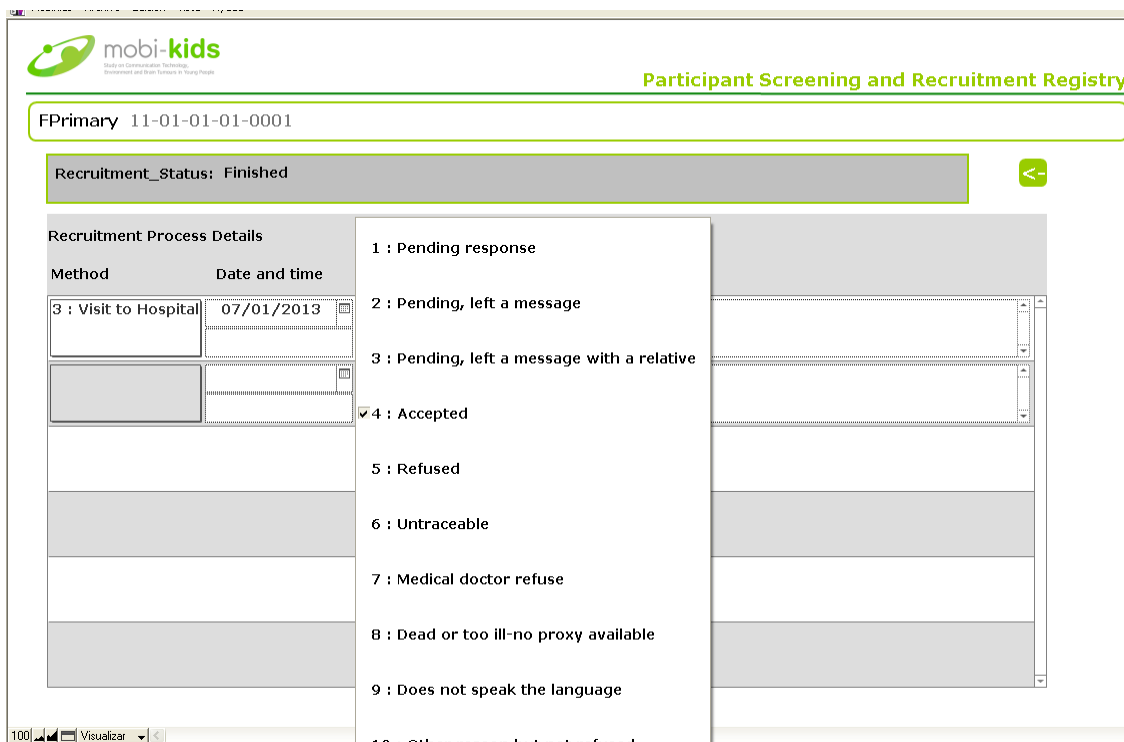
An electronic database application (following the paper questionnaires) has been developed to assist with interviews. Since many centres began interviewing cases and controls using paper versions of the questionnaire, these needed to be double-entered into the electronic application. This document provides the status of data collected and entered into the electronic application from MOBI-Kids centres as of April 2013.

1.1. Summary of database completion

The numbers of cases and controls who have been registered in the electronic database as identified and either interviewed or refused to participate by centre as of April 2013 are provided in Annex I.

Currently, two of the fifteen countries have not begun data collection. New Zealand received funding in May 2012, and is in the process of setting up the study infrastructure. India only very recently received funding to begin the steps necessary to start subject recruitment. Taiwan began data collection in April 2013.

For the countries who have recruited subjects, a total of 504 identified cases with 414 accepted and 63 not accepted (including refusals and pending), and a total of 1080 identified potential controls with 699 accepted and 263 not accepted are registered in the electronic application. All of the follow-up information on participants is included in the application (see screenshot below), with the exception of Israel who keeps recruitment information in a separate file. Austria and Taiwan are currently the only centres not using the application in real-time; both centres are finalizing the translation and centre-specific changes to the application.




Participant Screening and Recruitment Registry

FPrimary 11-01-01-01-0001

Recruitment_Status: Finished

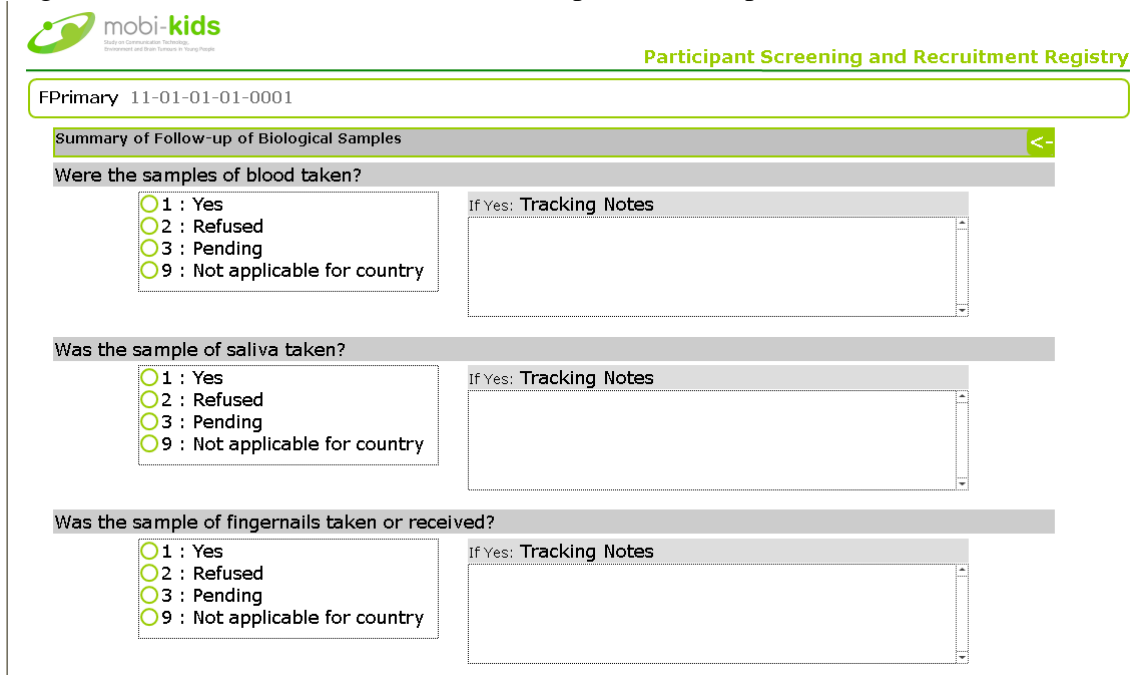
Recruitment Process Details	
Method	Date and time
3 : Visit to Hospital	07/01/2013

- 1 : Pending response
- 2 : Pending, left a message
- 3 : Pending, left a message with a relative
- ✓ 4 : Accepted
- 5 : Refused
- 6 : Untraceable
- 7 : Medical doctor refuse
- 8 : Dead or too ill-no proxy available
- 9 : Does not speak the language
- 10 : Other reason but not refused

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Before February 2012, all interviews were collected with the paper version of the questionnaires. After translating and training interviewers to use the electronic application, centres began administering questionnaires in real-time using the application starting in February 2012. Centres have completed back entry of paper questionnaires; in some centres double-entry of paper questionnaires is still underway. Issues revolving around older versions of the application have been resolved, and the application is in good working order with all centres having a single complete database. Before uploading the back-up files of the centre’s database to CREAL’s secure FTP server, coordinators separate the identifiable information by pushing a button on the application. This removes information such as names, phone number(s), email address(es), previous residences, etc, and creates an anonymous database. These anonymized databases were merged in January 2013 to one central database kept at CREAL and is being updated periodically and on request from CREAL to centres.


In addition, centres that are collecting biological samples register the samples in the electronic application (see screenshot below). The numbers of subjects with biological samples by centre registered in the electronic database as of April 2013 are provided in Annex II.

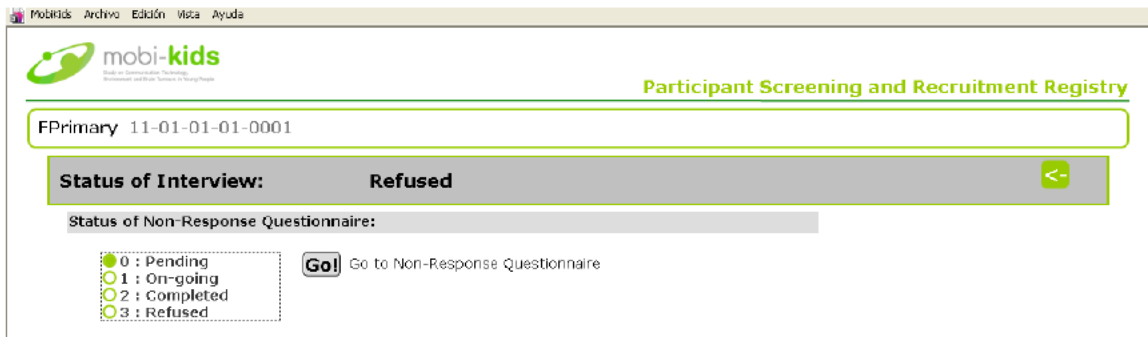


The screenshot shows the 'Participant Screening and Recruitment Registry' interface. At the top, there is a search bar with the text 'FPrimary 11-01-01-01-0001'. Below this is a section titled 'Summary of Follow-up of Biological Samples'. This section contains three questions, each with a set of radio button options and a text area for 'If Yes: Tracking Notes':

- Were the samples of blood taken?**
 - 1 : Yes
 - 2 : Refused
 - 3 : Pending
 - 9 : Not applicable for country
- Was the sample of saliva taken?**
 - 1 : Yes
 - 2 : Refused
 - 3 : Pending
 - 9 : Not applicable for country
- Was the sample of fingernails taken or received?**
 - 1 : Yes
 - 2 : Refused
 - 3 : Pending
 - 9 : Not applicable for country

In the event a case or control refuses to participate, they are asked to answer a short non-response questionnaire (NRQ). This is also kept in the electronic application (see screenshot below). The numbers of subjects with NRQs by centre registered in the electronic database as of April 2013 are provided in Annex III.

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Participant Screening and Recruitment Registry

FPrimary 11-01-01-01-0001

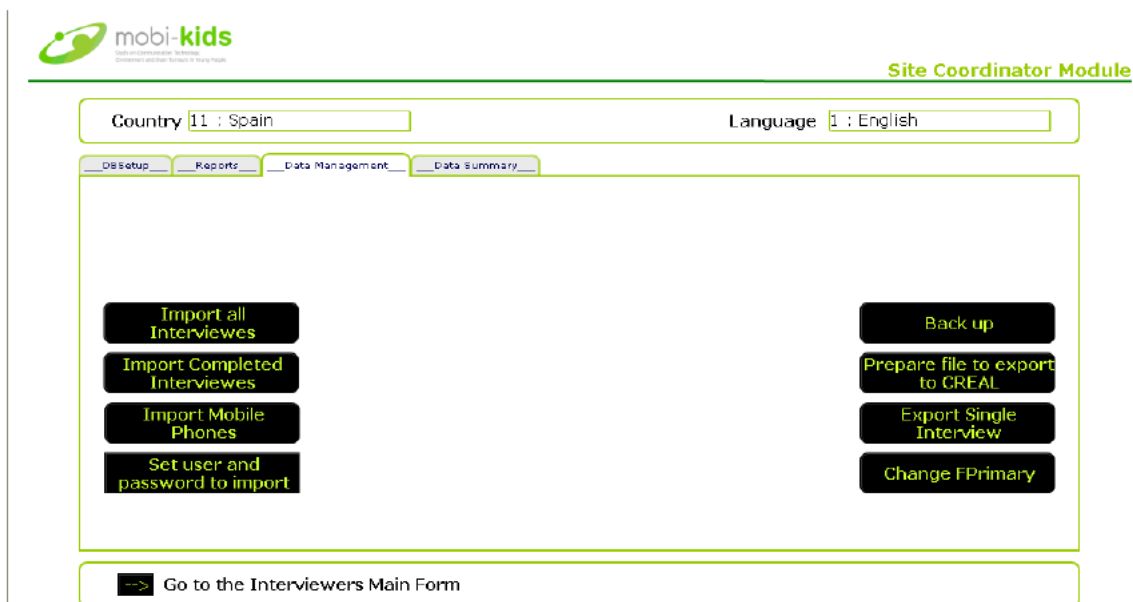
Status of Interview: Refused <

Status of Non-Response Questionnaire:

0 : Pending
 1 : On-going
 2 : Completed
 3 : Refused

Go! Go to Non-Response Questionnaire

In addition to follow-up information about participant’s status (of both questionnaires and samples), the data management section for site coordinators is finalised. From the site coordinator screen (see screenshot below), site coordinators are able to export subjects’ follow-up information to their interviewers, import interviews from their interviewers, and export anonymized interviews to CREAL via FTP.




mobi-kids
 Health Communication Technology
 Empowering and Enabling Families to Stay Healthy

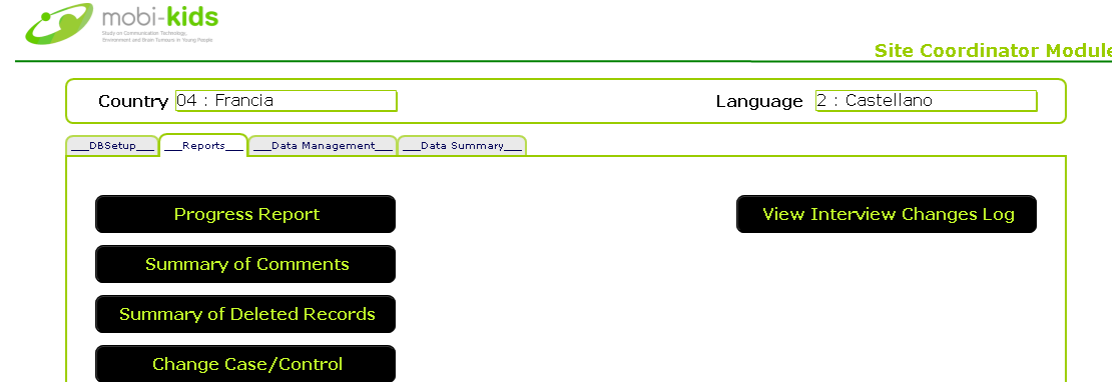
Site Coordinator Module

Country Language

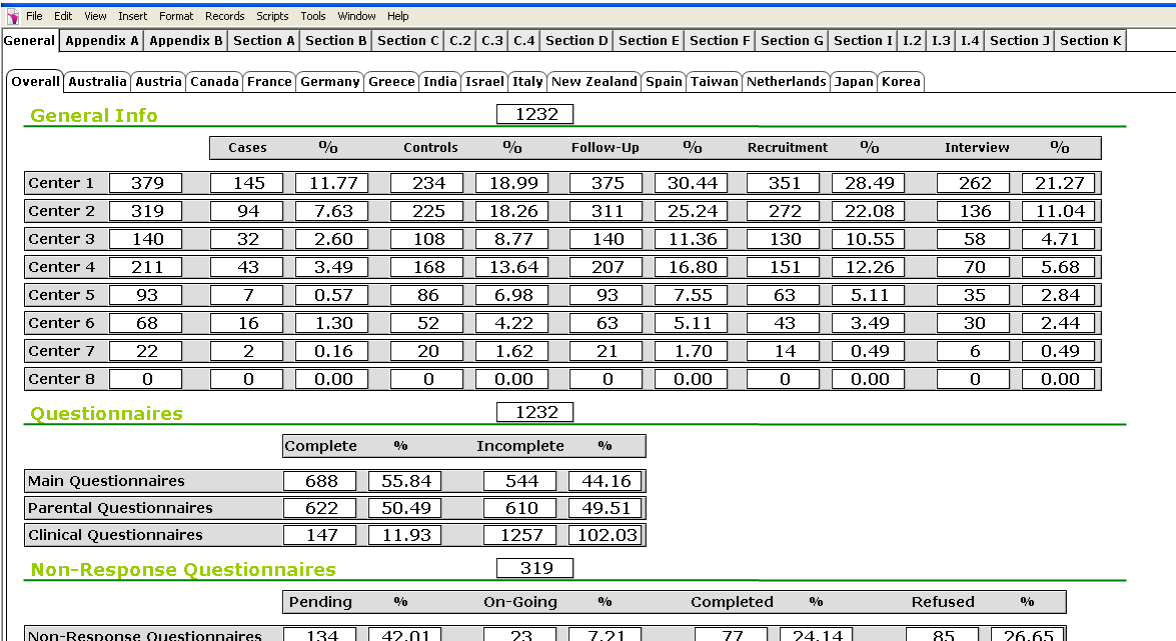
DB Setup Reports Data Management Data Summary

In addition, from the site coordinator screen under the “Reports” tab (see screenshot below), coordinators can review the log of changes recorded in the database (e.g., if an interviewer looked up a postal code and added it after the interview was complete), change the identification number of a participant if necessary, and view summaries of the comments and any deleted records.

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Finally, work has begun on validation checks (e.g., to check double-entered questionnaires for any inconsistencies – part of Deliverable 3.3) and progress reports, including response distributions for the entire questionnaire (see screenshot below) for Deliverable 3.2.



Overall: Australia, Austria, Canada, France, Germany, Greece, India, Israel, Italy, New Zealand, Spain, Taiwan, Netherlands, Japan, Korea

General Info 1232

	Cases	%	Controls	%	Follow-Up	%	Recruitment	%	Interview	%	
Center 1	379	145	11.77	234	18.99	375	30.44	351	28.49	262	21.27
Center 2	319	94	7.63	225	18.26	311	25.24	272	22.08	136	11.04
Center 3	140	32	2.60	108	8.77	140	11.36	130	10.55	58	4.71
Center 4	211	43	3.49	168	13.64	207	16.80	151	12.26	70	5.68
Center 5	93	7	0.57	86	6.98	93	7.55	63	5.11	35	2.84
Center 6	68	16	1.30	52	4.22	63	5.11	43	3.49	30	2.44
Center 7	22	2	0.16	20	1.62	21	1.70	14	0.49	6	0.49
Center 8	0	0	0.00	0	0.00	0	0.00	0	0.00	0	0.00

Questionnaires 1232

	Complete	%	Incomplete	%
Main Questionnaires	688	55.84	544	44.16
Parental Questionnaires	622	50.49	610	49.51
Clinical Questionnaires	147	11.93	1257	102.03


Non-Response Questionnaires 319

	Pending	%	On-Going	%	Completed	%	Refused	%
Non-Response Questionnaires	134	42.01	23	7.21	77	24.14	85	26.65

Periodic data downloads will be provided to CREAL for quality control and to inform the exposure assessment plan. The site coordinators will be able to produce progress reports and manage data from the site coordinator screen (shown below).

2. CONCLUSION

Data collection is well underway in most centres. Centres who have received funding (all countries dependent on receiving funding are outside the EU) are moving forward with data collection, and the queries for progress reports are finalised making future reporting much faster.

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ANNEX I: Summary Database Completion (April 2013)

Country	Partner/Institution	CASES (n°)			CONTROLS (n°)			Starting Date
		Identified	Accepted	Not accepted	Identified	Accepted	Not accepted	
Australia	MONASH	7	7	0	3	3	0	
Austria**	MUV							
Canada	UOTTAWA	2	1	1	0	0	0	
France	ARECEA	44	41	3	70	53	17	
Germany	LMU	76	48	19	113	63	23	
Greece	UOA-SARG	78	56	11	79	74	5	
India	TMH	N/A	N/A	N/A	N/A	N/A	N/A	2013 May
Israel*	Gertner	53	53	0	95	95	0	
Italy	UNITO	68	63	4	109	84	20	
Japan	TWMU	18	13	5	154	93	61	
Korea	DUCM	21	21	0	41	24	17	
New Zealand	AUCKLANDU	N/A	N/A	N/A	N/A	N/A	N/A	2013 June
Spain	CREAL	122	102	15	398	194	119	
Taiwan**	NTU							2013 April
The Netherlands	UU	11	5	5	11	10	0	
Total	--	500	410	63	1073	693	262	

N/A is entered when the study centre has not begun data collection yet and therefore there is no data to report.

*No refusals are entered into the electronic application because the recruitment information is kept separate from the central database.

**Finalisation of the electronic application is pending; thus, no information is available in the centralised database.

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ANNEX II: Summary Status of Biological Samples Registered in Database (April 2013)

Country	Partner/Institution	Subjects – biological samples			
		Accepted (cases and controls)	Blood	Saliva	Nails
Australia**	MONASH	10	0	6	0
Austria***	MUV				
Canada**	UOTTAWA	1	0	0	0
France	ARECEA	94	0	0	0
Germany	LMU	111	0	0	0
Greece	UOA-SARG	130	0	0	0
India**	TMH	N/A	N/A	N/A	N/A
Israel	Gertner	146	0	0	0
Italy**	UNITO	147	0	79	0
Japan	TWMU	107	0	0	0
Korea	DUCM	45	0	0	0
New Zealand	AUCKLANDU	N/A	N/A	N/A	N/A
Spain**	CREAL	296	0	253	155
Taiwan***	NTU				
The Netherlands**	UU	15	0	3	0
Total in centres collecting samples		469	0	341	155

N/A is entered when the study centre has not begun data collection yet and therefore there is no data to report.

**Centres that are collecting biological samples.

***Finalisation of electronic application is pending and thus no participants are registered.

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ANNEX III: Summary Status of NRQs Registered in Database (April 2013)

Country	Partner/Institution	Refusals	Non-Response Questionnaires		
			Pending	Complete	Refused
Australia	MONASH	0	0	0	0
Austria	MUV				
Canada	UOTTAWA	0	0	0	0
France	ARECEA	20	3	15	2
Germany	LMU	42	15	15	12
Greece	UOA-SARG	16	12	0	4
India	TMH	N/A	N/A	N/A	N/A
Israel*	Gertner	0	0	0	0
Italy	UNITO	24	2	19	3
Japan	TWMU	66	2	0	64
Korea	DUCM	17	7	1	9
New Zealand	AUCKLANDU	N/A	N/A	N/A	N/A
Spain	CREAL	134	56	61	17
Taiwan	NTU				
The Netherlands	UU	5	5	0	0
Total	--	325	103	111	111

N/A is entered when the study centre has not begun data collection yet and therefore there is no data to report.

*No refusals are entered into the electronic application because the recruitment information is kept separate from the central database.