2. Core of the report

2.1 Project objectives for the period

Specific project objectives were not listed per reporting period in the MOBI-Kids Description of Work. The following, however, were the original objectives for months 31 through 48, per work package:

WP1: Scientific coordination and conduct of the epidemiological study

To coordinate the overall project as well as to continue data collection, including questionnaires and biological samples from cases and controls.

To collect validation data from operators and MRIs and/or CTs to be used in the tumour localisation study.

WP2: Finalisation of the study instruments

To update study documents as needed based on input from fieldwork.

To prepare and finalise the code books for analysis and the analysis protocol.

WP3: Quality assurance

To ensure adequate quality control procedures for the conduct of the study.

To set up the procedures for and to verify tumour diagnosis and tumour localisation.

To validate questionnaire responses and data collected.

To validate exposure assessment work.

WP4: Exposure assessment

To complete RF measurements and modelling, and develop an exposure gradient.

To complete ELF measurements and modelling, and develop an exposure gradient.

To finalise Gridmaster head models and exposure databases.

To develop a strategy for assessment of exposures other than ELF/RF.

WP5: Data analysis and management

To finalise and implement the study database, including validation tools for real-time checking of data during the interview.

To periodically update the main database with centres' data.

To develop and finalise programs for estimating exposure.

WP6: Dissemination

To undertake dissemination activities according to the communication plan.

WP7: Project management

To support the Scientific Coordination in the follow-up of the workplan and in Consortium management issues, especially through amendments to the contract as necessary, financial management, and organisation of meetings of the Consortium, Subcommittees, and Task Group.

Both reviewers of the mid-term report (covering months 13-30) expressed the need for a time extension for MOBI-Kids to finish case and control ascertainment. Given the delays in obtaining all ethics approvals and the logistic difficulties in setting up such a complex study, the objectives listed above could not be completely met and the Consortium (as noted in the mid-term report) recognises the need to extend data collection to achieve the objectives and optimise the efforts invested in this important project. An extension for the

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exposure assessment would also be important since, with the joining of Japan and Korea, a more detailed exposure assessment plan has been proposed, building upon the expertise of collaborators in these countries, and leading to improvements in exposure gradients compared to those originally planned.

A time extension of 18 months or two years was discussed at the 4th Consortium meeting, but before formally asking for a (no-cost) time extension, we needed to be sure centres could in fact cover the expenses. Now that almost all centres have adequate funding to continue, and that several additional countries have funding and have recently started data collection, we will formally ask the Commission for a time extension shortly to meet the original objectives of the study. Once we have formal permission, we will inform stakeholders of the revised schedule as suggested by one reviewer.

One reviewer stated the need to prioritise the publication of the study design and methods. Work is well underway on this manuscript; it is expected to be submitted for publication in the summer 2013. A number of manuscripts on the exposure assessment methodology are also in preparation or submitted.

One reviewer noted the early indications of low recruitment – either because the infrastructure was still being put in place or because we had over-estimated the numbers in the original DOW. We have invested a lot of time and effort in this reporting period to understand why the recruitment is lower than expected, and when possible, take steps to alleviate this. Please see WP1 for more details. As suggested by the reviewers, we have submitted multiple updates on case-control recruitment in each country.

As both reviewers commented on the importance of hospital participation (including refusals), case ascertainment procedures (paediatric versus adult), representativeness of controls, time between diagnosis and interview, and participation among cases and controls in each country, we have been monitoring these issues through site visits, Skype calls, and email. Monitoring will continue throughout the course of fieldwork.

A reviewer commented that it is important to “ensure clear priorities are set out for analysis, laid out in an analytical protocol detailing how the RF and ELF modelling will be incorporated into epidemiological models.” With this in mind, at the 4th Consortium meeting an analysis task group was named to work on an analysis plan and the outline of the analysis protocol will be presented at the 5th Consortium meeting in May 2013. Please see WP2 for more details.

2.2 Work progress and achievements during the period

WP1 – Scientific coordination and conduct of the epidemiological study

WP leader: [redacted] – CREAL

Participant number	**1**	3	6	7	8	9	10	11	12	13	14
Participant short name (WP leader in bold)	**CREAL**	UU	LMU	MUV	UNITO	ARECEA	UOA-SARG	GERTNER INSTITUE	UOTAWA	MONASH	AUCKLAND UNI
Person-months per participant	**38.51**	12.5	25	4	15.1	30.07	10.84	13.2	20.6	29	6

During this reporting period, this work package focused on two important and complementary aspects: the overall scientific coordination of the project as well as the conduct of the study in all countries.

Overall scientific coordination of the project

Work on this aspect was primarily accomplished through study meetings and site visits. There was a full consortium meeting in April 2012. This meeting allowed for a thorough discussion of the study protocol. Strategies to deal with issues arising from the field were developed during the course of the full consortium meeting. In addition, a fieldwork coordinators meeting was conducted in April 2012, providing a forum for discussion of nuances of the protocol and questionnaire, as well as other issues arising during fieldwork. Three meetings of the epidemiology and exposure assessment subcommittees were held in October 2011, and April and November 2012, respectively.

[redacted] conducted nine site visits in 2012: Japan (February/March), Korea (March), Greece (March), the Netherlands (April), Germany (April), Austria (June), Italy (July), Israel (July), and Canada (October), In addition, three more are planned in spring 2013: France (March), New Zealand (April), and Australia (April). The remaining site visits (India and Taiwan) will be planned pending confirmation of the centres' funding situations. As [redacted] is in Spain, a site visit per se has not been conducted as both [redacted] and [redacted] (who is also [redacted] for Spain) interact regularly with [redacted] and attend the meetings of the regional PIs and those of the regional fieldwork coordinators.

In conjunction with a site visit, an interviewer training was conducted in centres that either recently began or intended to commence shortly case ascertainment: Japan, Korea, and Canada. A similar training is planned for New Zealand in anticipation of their imminent start of fieldwork. These trainings were designed to further prepare the coordinators to hold interviewer training workshops in their own local language (if applicable), to deliver questionnaires, and to familiarise them with the questionnaires' content and approaches to contact study subjects.

In addition to meetings and site visits, [redacted] and [redacted] maintained contact via Skype, e-mail, phone calls, and discussions on the occasion of other meetings and conferences with all partners to monitor and discuss progress and difficulties.

Conduct of the study in all countries

Progress of the work is described by country below.

Australia (MONASH)

The Australian investigators are [redacted] Monash University), [redacted] (University of Sydney), and [redacted] (University of Western Australia), and [redacted] (Monash University). [redacted], appointed August 2010, is [redacted] (Monash University). There has been a change in staff with the appointment of a new project officer to assist with patient recruitment and an interviewer for Melbourne and Sydney respectively.

Funding of $693,550 for five years was awarded by the Australian National Health & Medical Research Council (NHMRC) under the NHMRC-EU grant program to support Australian involvement in the study, including collection of the data from Australian cases and controls.

Ethics and Governance approval has now been granted for all participating hospitals. There are ten participating case hospitals (five each in Melbourne and Sydney) and 27 control hospitals (12 in Melbourne and 15 in Sydney).

In total to date, 21 potential cases have been identified; five have been successfully interviewed and six are still in the recruitment pool though two of these have interviews arranged. Seven cases were not approached due to: final diagnosis indicating ineligible tumour type or recurrence (four); mental distress (two); and one did not speak English. Potential cases must be approved by their surgeon as being fit to participate before the study team is allowed to approach. One case did not respond and there were two refusals.

Twenty-three potential controls have been identified to date: three controls have been interviewed; 12 are still in the recruitment pool; and four controls were not approached (two were mentally unwell and two were discharged before the registrar could make an approach). In addition, there were three refusals and one control remains untraceable.

Austria (MUV)

The Austrian investigators are [redacted] and [redacted]

Activities during the reporting period focused on receiving ethics approvals to begin fieldwork. Ethics applications have been submitted for ten hospitals (in Vienna, Lower Austria, Graz, Tyrol, and Vorarlberg); for two additional hospitals applications have been prepared (Upper Austria). Multiple responses to the ethics committees' feedback have been submitted. Ethics approvals for hospitals in Vienna, Lower Austria, Tyrol and Vorarlberg are finalized. Ethics for Graz and Upper Austria are still under review. Contact persons for all participating individual hospitals were informed in case of personnel change: the aim was to discuss their participation in detail and to finalize the recruitment procedures respecting the guidelines set by each local ethics committee. Contacts included visits of hospitals and continuous motivation.

One neurosurgery department has refused participation. This neurosurgery does not treat children. However, we will be notified if an eligible patient is treated there and can contact the patient ourselves. Identifying gaps in the hospitals' daily routine led to setting up Standard Operating Procedures for recruiting and obtaining informed consent in partner hospitals.

An umbrella organization of mobile phone operators (in order to get information about available operators' data) was contacted. They agreed to provide data for the previous six months of telephone traffic.

A refresher interviewer training has been performed. Data collection officially started in June 2012 (after ethics approval of the Medical University Vienna) using paper versions of the questionnaires.

Two glioma cases and four controls have been identified and contacted. One case in Tyrol was rejected due to an ineligible diagnosis (craniopharyngioma). Both eligible cases were interviewed; controls are scheduled for March/April 2013.

Finally, the project has been presented at the Environmental Medicine Course of the Austrian Chamber of Physicians and at the 4th International Conference on Risk Analysis.

Canada (UOTTAWA)

The Canadian investigators are University of Ottawa), (Ottawa Hospital Research Institute), (British Columbia Cancer Agency), (Cancer Care Ontario), and

The Canadian research team received approval for funding in April 2011 with a grant from the Canadian Institutes of Health Research (CIHR) in partnership with the Canadian Wireless Telecommunications Association (CWTA).

In Canada, three centres (University of Ottawa, Cancer Care Ontario in Toronto, and British Columbia Cancer Agency in Vancouver) have agreed to participate in the study. An interviewer training workshop was held in Ottawa in October 2012. The investigators and local coordinators attended the meeting and discussed the application of the study protocol for Canada in anticipation of beginning case ascertainment.

Each centre has met with physicians at hospitals to discuss their participation and to finalise the recruitment procedures respecting the guidelines set by each local ethics committee. Local procedure and recruitment study protocols have been finalised in each centre. Ethics applications have been submitted for the main children's and adult hospitals. Ethics applications have been approved for the adult hospitals at three of the sites, and ethics applications for the children's hospitals have been approved at two of the three sites (Ottawa and Vancouver). Toronto expects to obtain approval in the next few months.

The project team has been scheduling monthly conference calls to discuss the study progress and any issues that arise. In addition to a team meeting held in France in April 2012 (in conjunction with the full Consortium meeting), there will be a team meeting and workshop held in Spain in May 2013 (as before, in combination with the full Consortium meeting).

In total, seven potential cases have been identified; two have been successfully interviewed and four are still in the recruitment pool. One case has refused. Two controls have been identified and are still in the recruitment pool.

The Canadian team also has an agreement with the three main network operators to access billing records from subjects who provide consent to participate in the retrospective validation study.

France (ARECEA)

The French investigators are [redacted] ARECEA), [redacted] (IFSTTAR), and [redacted]

Work in France during the third reporting period has been primarily dedicated to participant recruitment to complete triplets (one case and two matched controls). As detailed in the previous report, difficulties were encountered in obtaining agreements for study participation from private hospitals and clinics. Efforts have been undertaken (visit the institutions; and repeated requests by mail, e-mail, and phone) successfully to obtain some participating private institutions.

Throughout the reporting period, case and control recruitment took place normally in all regions except in Alsace where, due to difficulties finding a long-term interviewer, recruitment only began in September 2012. In addition, Gironde, in the southwest of France, was included in MOBI-Kids to increase the catchment area. As in Alsace, the recruitment in this new area began in September 2012.

Recruiting controls has been more difficult than for cases, primarily due to: (i) lack of interest of some visceral surgery services which are less interested in a study of brain tumours; (ii) limited participation of private institutions; (iii) the matching criteria which complicates the recruitment; and (iv) the very short duration of hospitalization for appendicitis. To overcome these difficulties, permission was granted from the National Commission for Information Technology and Civil Liberties (CNIL) to retrospectively identify controls based on PMSI data from the institutions concerned.

Three national meeting for interviewers were held in Paris during this period to review in detail the study methodology (inclusion and exclusion criteria, data collection) and the progress of the study, as well as to train interviewers in the use of the electronic application. The next national meeting is planned in April 2013.

Data collection began with a paper version of the questionnaires (participant, parents and clinical). Quality control checks of these paper copies highlighted some errors that required contacting the participants to clarify responses. Some oversights would have been avoided through control elements available in the electronic application. A large effort was carried out in early 2012 to allow using the electronic database (in use in the field starting in June 2012). Currently, 40 cases and 56 controls have been interviewed.

MOBI-Kids France has established an active collaboration with the three main network operators in the country regarding their participation in the validation study of mobile phone use. Data exchanges are performed once a month (usually around the 15th). A new operator appeared on the market in France in January 2012 but its collaboration is not feasible at the moment as several data needed for the study are not technically available, e.g., frequency, antenna location, etc.

Germany (LMU)

The German investigators are [redacted] and [redacted]

After case recruitment began slowly over the first months of the study, in 2012 recruiting more collaborating hospitals was emphasized. The rationale for expanding the network of

hospitals is the widespread treatment of brain cancer cases throughout Germany. In contrast to our initial assumption that most cases are treated in a few centres, cases are treated in many different hospitals. Each of these hospitals treats just one to four cases per year, making the widespread inclusion of hospitals a must and further complicating the logistics of recruiting cases and controls.

In February 2013, 63 cooperating departments (primarily paediatric and adult neurosurgery) in 45 hospitals were contributing to case recruitment. Some cooperating requests are still outstanding; therefore, the network is expected to expand in the next weeks. With respect to the control recruitment, 68 departments in 59 hospitals were participating in MOBI-Kids as of February 2013. The number of control hospitals might also increase over the next weeks.

To date, 90 cases were identified from the cooperating hospitals. Of these, 83 met the inclusion criteria. Of these 83 eligible cases, 58 agreed to participate and 16 are pending a decision. By the end of February, 47 of the 58 agreed subjects had completed interviews. Of 127 identified controls, 63 agreed to participate. Of these, 58 have completed interviews.

To further increase the number of cases, we initiated a collaboration with the German childhood cancer registry. Using the registry information will allow us to determine the number of cases not reported to us by the cooperating hospitals. These hospitals can then be reminded by the German childhood cancer registry to report the cases to us.

Greece (UOA-SAGR)

The Greek investigators are [redacted] and [redacted]

Overall, the project team has devoted efforts to: maintain and expand the network of local partners contributing data; identify gaps in the daily routines of the project implementation and ensure maximum adherence with the study protocol adjusting for the Greek conditions; correspond with [redacted] and leadership of the project and host the site visit of [redacted] in March 2012; train substitute [redacted], notably [redacted] and [redacted]; complete the environmental exposure inventory and contact mobile telephone providers for the operator validation study; conduct a quality control study to identify completeness of recruitment for children aged 10-14 years old, and proportion of adolescents and young adults aged 15-24 years old who might have been treated in the main private hospitals (given that cases may be handled in private hospitals and there is no functional national cancer registry in Greece); disseminate preliminary results at national conferences; and participate in the annual MOBI-Kids meetings.

Specifically, a total of 53 units within 35 hospitals and clinics were identified across the country to potentially provide cases and/or controls and applications were submitted to the local ethics committees. The applications were followed-up to ensure verbal approval first and then written approval in most instances. There was no objection for any application. Furthermore, in response to administrative delays, a recent decree (FEK 390, 21-2-2013) was issued related to clinical studies in Greece stating that following submission of the application, the application is considered as approved if there is no written objection on the part of the respective Committee within a 30-day period.

Childhood (0-14 years) brain tumours are most likely to be treated at some stage at the paediatric haematology-oncology departments comprising the Nationwide Registry for Childhood Haematological Malignancies (NARECHEM, http://narechem.gr/) functioning in

our department since 1996. In contrast, brain tumours in adolescents and young adults aged 15-24 years can be diagnosed in dispersed medical establishments across the country. Therefore, to maximize recruitment of cases and degree of completeness in the different age groups, we dedicated time and effort to expand the network by inviting neurosurgeons, neurologists, radiologists, radiotherapists, oncologists and intensive care unit internists from all seven medical schools to participate. In addition, regular personal contact with each department both in public and private hospitals across the country was maintained. Clinicians were expected to contact the pathology departments of the collaborating hospitals, but the results thus far have been rather poor.

A total number of 80 incident brain tumour cases were identified during the recruitment period. As case recruitment in Greece comes to an end, it is noted that the refusal rate was rather low. However, 28 of these incident cases were notified at a later time than that provisioned by the protocol. Out of them 8 cases were interviewed, whereas interview could not be scheduled for 19 cases either because contact was lost (8 cases) or because the time frame since first diagnosed was overdue (7 cases) or they refused to collaborate (5 cases). Clinical data are readily available for 36 cases and pending for 43 cases, whereas 1 of the 80 incident brain tumours was excluded as the treating physician eventually informed us that it was first diagnosed in 2008. Furthermore, according to the final inclusion criteria of the project, some types of tumours were deemed ineligible due to histology or later start of the formal data collection and are to be excluded from the analyses. A total of 98 controls have been interviewed, out of whom 28 are age matched for about 1-5 months difference compared to the eligibility criteria. Selection of controls has been intensified. Due to local conditions, a dual system of computerized and paper collection of data has been used.

The neuroradiologists who will perform the tumour localization assessment have been identified. In anticipation of the Gridmaster development, which will allow the tumour localization, we need to verify that each participating centre will have the initial MRI available (as the image might be held by the families themselves).

Israel (GERTNER INSTITUTE)

The Israeli investigators are [redacted] and [redacted].

In Israel, there are six neurosurgery departments, five of which have given their consent for participation in the study. Controls are being identified from the five hospitals from which the cases are being identified and an additional five surgery departments in other hospitals, in order to have sufficient geographical coverage of controls. Approvals for changes and additions to the protocol were obtained and renewals are approved once a year.

Recruitment of brain tumour patients and matching controls was initiated in Israel in August 2010. In total, 84 brain tumour cases from the five medical centres have been identified. Among these, 72 are eligible for participation in this study (12 patients were excluded because either the date of diagnosis preceded the beginning of the study or because it was decided that their particular morphological subtype would no longer be included in the study). So far, out of the 72 eligible cases, 13 refused participation and 59 cases have provided consent for participation, with 56 having completed interviews.

For the 59 participating cases, 204 eligible controls from ten medical centres were identified. Of these, 100 were interviewed, 85 refused to participate, 16 are still being processed and three could not be traced.

Non-response questionnaires (NRQs) are being administered to all identified cases and controls who refuse to participate in the study. Until now, 13 cases and 85 controls refused to participate in the study. Out of the 98 refusals, 88 were approached and asked to complete an NRQ over the phone. Five cases and 47 controls (60%) completed the NRQ. Thirty-three percent refused to complete the NRQs and 8% were lost to follow up.

In Israel, the participants are interviewed by three interviewers who were trained in the administration of the questionnaires in the study centre. Periodic local workshops are conducted once a month to ensure consistent reliability of the data collection.

Until now, 56 cases and 100 controls were interviewed with complete sets of questionnaires. All questionnaires are checked for completion and then entered in the computerized data set. Since the beginning of 2013 most of the interviews are being conducted using the computerized application.

MRI and CT reports are being collected; the images will be reviewed when the program for tumour localization data is ready.

Italy (UNITO)

The Italian investigators are and .

The study in Italy is conducted in four regions: Piedmont, Lombardy, Emilia-Romagna, and Tuscany. Tuscany and Emilia-Romagna began case ascertainment in September 2011; Lombardy began at the end of January 2011; and Piedmont began in August of 2011.

During the reporting period, applications to local ethics committees were finalized. Currently, ethics have been approved in 30 out of the 34 case hospitals and in 36 out of 39 control hospitals.

At present, a total of 65 cases and 86 controls have completed interviews. Five cases refused to participate, and three of these have completed the NRQ. 19 controls refused to participate (17 have completed NRQ) and 5 controls were determined to be untraceable after numerous attempts to reach them by telephone.

Biological samples (Oragene saliva) were collected for 50 cases; MRI and CT reports are being collected and all images have been requested and stored when immediately available.

All the main network operators in Italy (Vodafone, Tim, Wind and H3G) have agreed to participate in the validation study, providing data for the last 15-24 months of telephone traffic.

New Zealand (AUCKLANDUNI)

The New Zealand team includes All three are based at the Centre for Public Health Research, Massey University, Wellington. Other investigators include (School of Public Health; University Of Auckland); (Auckland Medical Specialists; and University of Auckland); (Centre for Public Health Research; Massey University); (Centre for Public Health Research; Massey University); and (Department of Medical Statistics; London School of Hygiene and Tropical Medicine).

Funding of NZ$103,265 was awarded by Cure Kids New Zealand, and an additional NZ$466,148 was awarded by the New Zealand Health Research Council to support New

Zealand's involvement in the study, including collection of the data from New Zealander cases and controls.

New Zealand has five neurosurgical units servicing a population of 4.4 million: Dunedin (since 1943) 3 neurosurgeons; Auckland (since 1945) 6 neurosurgeons; Wellington (since 1965) 4 neurosurgeons; Christchurch (since 1981) 4 neurosurgeons; Hamilton (since 2006) 4 neurosurgeons.

The study will be conducted in all five centres, pending approval, with Auckland and Christchurch forming the largest. Wellington, Auckland, Christchurch and Dunedin have been contacted and procedures for approval of the research project are underway. Ethical approval from the multi-region ethics committee has been applied for, and final approval is pending the approval of the individual centres.

Controls will be selected from the national hospitalizations data held by the NZHIS (New Zealand Health Information System), which is updated every 21 days, and which will enable identification of appendicitis controls living in the same area as the cases.

The main network operators in New Zealand are Vodafone, Telecom and 2degrees. Whether operator data can be obtained is currently being investigated.

Case and control recruitment is envisaged to start in the second half of 2013.

Spain (CREAL)

The Spanish investigators are CREAL), (University of Huelva, Andalucía), (Institute of Health Carlos III, Madrid), (University of Valencia), and

In Spain, the study is being conducted in four autonomous communities: Catalonia, Andalucía, Madrid, and Valencia.

In the four communities, 70 hospitals have been contacted (and submitted ethics approvals applications) to contribute cases; of these, 57 have agreed to participate, three have refused, and ten are still pending. For controls, an additional 17 hospitals were contacted (and submitted ethics approvals applications). Of these 17 hospitals, 11 agreed to participate, two refused, and four are pending.

The first interviews in Spain were conducted in February 2011 in Catalonia and Madrid. Up to now, 141 cases have been identified. Of these 141, 104 (74%) have accepted and been interviewed, 14 (10%) have refused, and 23 (22%) are pending. For controls, 394 have been identified. Of these, 189 (48%) have accepted and completed interviews, 100 (25%) have refused, 88 (22%) are untraceable after many attempts at contacting them over the telephone, and 17 (4%) are pending.

Quality control checks are performed periodically to ascertain completeness of case identification by checking the pathology and cancer registry. Using this method, an additional 16 cases were identified. These cases are recruited to participate in the study as long as their first image is within a year of their scheduled interview (following the decisions taken by the General Assembly at the 4th Consortium meeting). When approached with missing cases, the physicians expressed uncertainties about eligible diagnoses or other criteria (i.e., immigrants). In addition, has listened to recorded interviews conducted by all interviewers and provided feedback as necessary.

The Spanish team contributes to the collection of biological samples (Oragene saliva) for genetic analyses based on complementary national funding; to date, 251 saliva samples have been collected.

The main network operators in Spain (Orange, Telefonica, and Vodafone) have agreed to provide data. Depending on the operator the available data ranges from 45 days to one year. To date, 232 informed consents have been signed to release operator data.

The Netherlands (UU)

The Dutch investigators are [redacted] and [redacted]

During the reporting period, all participating hospitals granted local ethical clearance and started recruiting patients. In total, 12 hospital departments (oncology, neurosurgery, and neurology) in the Netherlands are recruiting cases: four departments recruit paediatric cases and eight departments contribute adolescent/young adult cases. Recruitment of controls is done in seven hospital departments (surgery, paediatrics): one department only recruits paediatric controls, while the other departments recruit controls from both paediatric and adult ages. Additional hospitals have been approached to participate in the study; their response is pending.

Collaboration has been established with the Dutch Childhood Cancer Parent Organisation (VOKK). In November 2012, the medical ethical committee of the University Medical Centre Utrecht (UMCU) approved additional recruitment of cases among the members and network of the VOKK. The cooperation with the Dutch Society for Paediatric Oncology (SKION) has been strengthened in that SKION employees send a monthly update to [redacted] with new eligible cases in the participating paediatric departments. For the departments that recruit adolescent cases, monitoring of new eligible patients is done by the physicians themselves or by their secretary.

Of the 14 eligible cases identified so far, four agreed to participate and have been interviewed, two are pending and eight dropped out for various reasons (three died, three refused, and two were untraceable). Out of the 12 controls contacted so far, nine agreed to participate and have been interviewed, two are pending and one refused to participate.

Additional medical ethical clearance was acquired from the UMCU in February 2012 for the collection of saliva samples. So far, three saliva samples have been collected.

All interviewed cases and controls also provided informed consent for the acquisition of operator data for the validation study on self-reported mobile phone use. In the Netherlands, one large operator recently agreed to provide aggregated mobile phone use data. Negotiations are still ongoing with two other large operators.

External countries (India, Japan, Korea, and Taiwan)

As Japan and Korea were funded after work had begun in the European centres, their work during this reporting period included: applying for ethics approvals at all of the selected case and control hospitals, translating the electronic database, training the interviewers and familiarising themselves with the electronic questionnaire, and beginning/continuing data collection. Japan and Korea began data collection in July 2011 and March 2012, respectively. In Japan, 13 cases and 95 controls have been interviewed; in Korea, 21 cases and 24 controls have been interviewed to date.

India and Taiwan will participate in MOBI-Kids pending confirmation of funding.

Deviations in schedule and use of resources

The original project schedule (see Gantt Chart in DOW) foresaw data collection finishing in the third reporting period, with case identification and control selection beginning in month 13 and ending by month 42. As indicated in the previous report, however, the logistics and ethical aspects of this complex study, which requires participation of numerous hospitals in each country, has led to an important delay in the start of work in all countries and a request for a no-cost extension is being prepared to ensure that the study will have sufficient power to fulfil its objectives.

Work in the current reporting period has gone well and numbers of interviewed cases and controls has increased substantially since the last report. Figures 1 and 2 show cumulative case and control recruitment for all centres, by month from start of data collection.

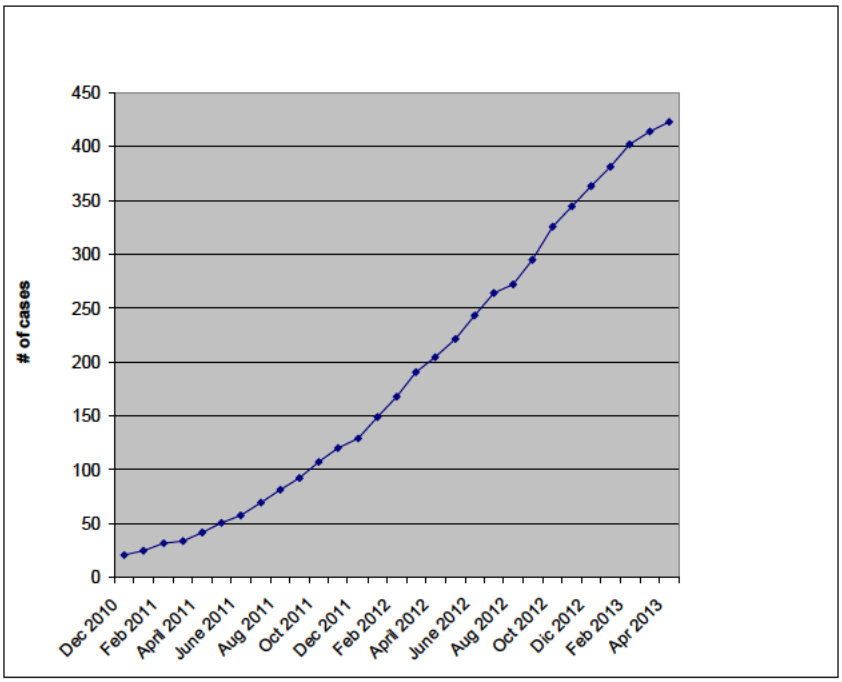

Figure 1: Cumulative total of cases interviewed for MOBI-KIDS

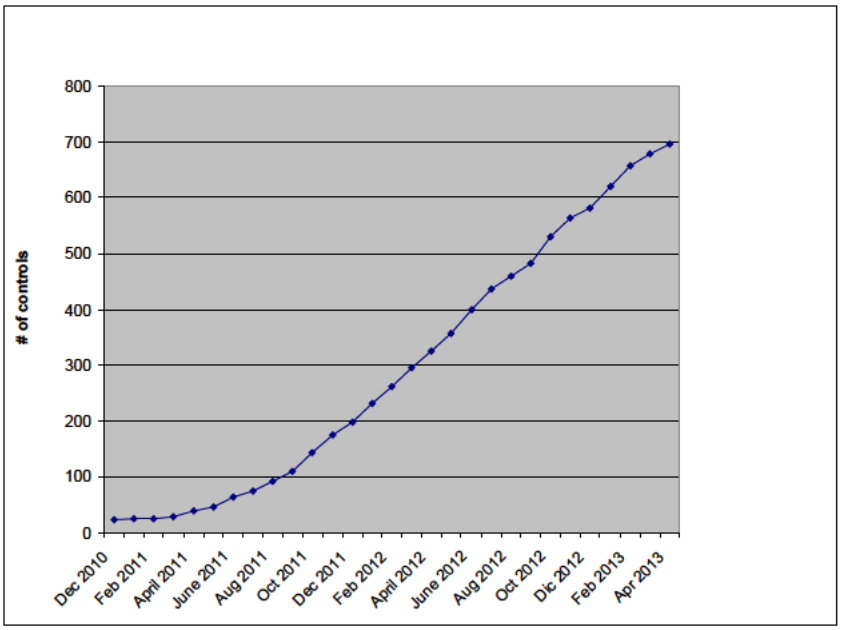

Figure 2: Cumulative total of controls interviewed for MOBI-KIDS

The table below shows the expected number of cases per year and for the study period by country versus the actual number of cases collected by country (among the countries that have started collecting data). Please note the table below is updated to April 2013 (numbers in the country-specific reports above are updated to the end of February 2013). An additional 80 cases per year (213 for the study period) are expected from countries that have not yet begun data collection. Despite the substantial increase in case ascertainment and interview in the current reporting period, actual numbers of cases are still considerably lower than originally anticipated.

Table 1: Expected versus actual number of cases by country

Country	Expected # of cases		Actual # of cases				Start of data collection
	Per year	Study period	Identified	Accepted	Refused	Pending	
Australia	71	178	16	8	6	2	Aug 2012
Austria	35	86	3	3	0	0	June 2012
Canada	94	234	7	2	1	4	Nov 2012
France	94	235	76	54	5	17	July 2011
Germany	125	313	92	69	9	14	Dec 2010
Greece	25	63	49	37	2	3	Dec 2010
Israel	40	120	75	61	14	0	Dec 2010
Italy	68	169	84	78	6	1	Feb 2011
Japan	50	75	19	13	5	1	July 2011
Korea	78	156	21	21	0	0	March 2012
Spain	125	313	140	113	14	10	Feb 2011
The Netherlands	63	158	14	4	8	2	Aug 2011
Total	**868**	**2,100**	**596**	**463**	**70**	**54**	

As mentioned above, a substantial effort has been made to understand the reasons for this. Reasons identified to date include: including only incident tumours (whereas registry data on which the estimated numbers were based include all tumours the year of diagnosis, regardless when the tumour was first noticed); uncooperative doctors; and excluding certain diagnoses.

Although the impact of these identified reasons is difficult to estimate precisely, in centres with access to updated hospital records approximately 10% of cases are either non-incident or are identified more than twelve months have passed since the first image showing a suspicion of a space-occupying lesion. Another approximately 5% of cases are lost due to uncooperative physicians (i.e., cases are identified through secondary sources in cooperating hospitals instead of the physician/hospital staff notifying MOBI-Kids staff directly).

The single most important reason identified to date for the discrepancy in numbers is excluding tumours originating in the midline. Although the original expected numbers are based on all malignant brain tumour cases aged 10 to 24 years (and 80% participation), the Consortium agreed to only include tumours originating in areas of the brain with high levels of exposure to RF and ELF. When the decision was taken, it was thought that the impact on number of cases would be small (roughly 1-2%). However, it appears that one-third to one-half of cases in this age group have ineligible diagnoses (based on the centres with reliable, detailed registry information). The discrepancies in numbers will continue to

be monitored and centres will record as precisely as possible all ineligible and missed cases.

The net result of these findings, however, is that the total number of cases that will be recruited is likely to be substantially lower – about 50% – than initially expected in the DOW. As this observation raises questions about the likelihood of the study to be informative, we have performed power calculations, using information collected by questionnaire from study subjects interviewed to date.

Approximately 15% of all subjects in MOBI-Kids have used a mobile phone for ten years or longer, the threshold for long-term use in INTERPHONE. This is higher than in INTERPHONE study subjects and higher than the estimation used in the original Mobi-Kids power calculations. Revising the power calculations using this as an estimate for exposure, and setting power at 80%, we need only 719 participants to detect an OR of 1.4. **Thus, with a time extension and with lower than expected numbers we expect the study to have sufficient statistical power to estimate an effect of mobile phone use on brain tumours, if there is an effect.**

Use of resources in WP1 is in line with the work conducted to date. Those countries just starting or about to start data collection reported the least effort and expenditure, as would be expected.

WP2 – Finalization of the study instruments

WP leader: [redacted] - GERTNER INSTITUTE

Participant number	1	6	8	9	**11**	14
Participant short name (WP leader in bold)	CREAL	LMU	UNITO	ARECEA	**GERTNER INSTITUE**	AUCKLAND UNI
Person-months per participant	7.75	1	1	0.2	**1.35**	1

The aim of WP2 is to finalize the study instruments, including preparation of the study questionnaires, preparation of show cards and documents for the conduct of the study in the participating countries, as well as preparation of the core protocol and validation of the finalized version.

The following is a description of the achievements of this work plan during the 3rd reporting period by tasks:

Core protocol

While in the previous reporting periods a significant amount of work was devoted to the development of the study protocol, in the current reporting period the study protocol was reviewed periodically and updates were and will be made in the future in accordance with specific issues and questions which arise from the field. Updates are sent periodically to the entire Consortium.

Preparation of data code book

The data code book or data dictionary is included automatically as part of the computerised questionnaire application (FileMaker Pro) and was completed in the 2nd reporting period. A number of minor changes to the questionnaire were made during the reporting period, thus resulting in small changes in the code book.

Preparation of analysis protocol

An analysis task group was nominated at the Consortium meeting in April 2012. It consists of: [redacted] (CREAL), [redacted] (Gertner), [redacted] (UU), [redacted] (UOttawa), and [redacted] (UOA-SARG). A preliminary outline of the analysis plan has been prepared. It will be discussed at the 5th Consortium meeting in May 2013, and developed based on feedback received at the meeting.

Deviations in schedule and use of resources

The development and optimisation of the study documents (protocol, procedures, questionnaires) has necessitated much more time than initially budgeted and revisions and updates need to be made periodically in order to deal with problems arising in the field, something which was not originally anticipated. Up till recently therefore, major efforts in this WP were concentrated on the development and optimisation of the study documents and the start of work on the analysis protocol was consequently delayed. Given the delay in data collection under WP1, however, it is expected that the analysis protocol will be

finalised in a timely fashion in the next reporting period, before data collection is completed and analyses begin.

Use of resources in WP2 has been in line with the work conducted to date.

WP3 – Quality Assurance

WP leader: [redacted] - UU

Participant number	1	**3**	6	8	9	11	14
Participant short name (WP leader in bold)	CREAL	**UU**	LMU	UNITO	ARECEA	GERTNER INSTITUE	AUCKLAND UNI
Person-months per participant	2.59	**1**	1	0.52	1.5	1.5	1

During the reporting period, the protocol for the validation study on self-reported mobile phone use with operator data has been further detailed, and the informed consent form has been improved and built into the electronic questionnaire. All countries have stated that they will join this validation study and are somewhere in the process of obtaining the operator data. Available information and format depends on the operator in each country; see table 2 for more details about information available in each centre.

A software modified smartphone (SMSP) study, Mobi-Expo, is underway (with separate funds) to assess the reliability and validity of self-reported mobile phone use SMSPs. Data collection began in October 2012 in Spain, The Netherlands and Australia. Currently, France and Germany are recruiting volunteers. The other countries are expected to take a turn in the coming year.

The validation study on brain tumour diagnosis is currently under discussion; the final protocol will depend on the main data analysis plan and the possibilities within each country to obtain and transfer detailed pathology data.

The protocol for the validation study on questionnaire data has been further developed. Validation checks have been built into the electronic questionnaire. Regular validity checks of collected questionnaire data have been delayed given the delay of finalising the questionnaire and getting the actual interviewing started in the centres. Since most centres are in the process of data collection now, the first validity checks will be produced as soon as possible and will be reported in Deliverable 3.2 and 3.3 shortly.

Deviations in schedule and use of resources

Work in WP3 has been delayed following the delays in finalising the study documents and in receiving ethics approvals (discussed in WP2), and subsequent delays in setting up the electronic database. Deliverables 3.2 and 3.3 have not yet been produced given the delay of finalising the questionnaire and starting data collection, as well as finalising, translating, and implementing the electronic database to have a central database (discussed in WP5). Since most centres are now recruiting cases, with a few more expected to begin soon, and are using the electronic database application, we will collect the necessary information and prepare these deliverables as soon as possible.

The used resources are in congruence with the amount of work performed so far.

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Table 2: Operator validation study – status and available data

Study centre	**Period of historical operator data available *(e.g. 1 year back)***	**Data available from network operators**	**Agreement and/or contracts signed with operators**
Australia	1 year back	Available: • Dates • The number of successful outgoing calls • Total duration of outgoing calls • Number of outgoing SMS/MMS • Total data traffic in kilobytes Partly available: • Frequency band: not available from the operators, but can be obtained from the model of the phone • TAC: only for outgoing calls • First and last base station: only first base station and only for outgoing calls	No agreement yet; expected Mid May 2013
Austria	6 months back	Only outgoing calls available Available data: • Dates • The number of successful outgoing calls • Total duration of outgoing calls • Number of outgoing SMS/MMS • Total data traffic in kilobytes • Frequency band: not available from the operators, but can be obtained from the model of the phone • TAC: only for outgoing calls First and last base station: only first base station and only for outgoing calls	FMK agreed to provide data
Canada	Depends on type of phone plan used by customer: 6 months - 7 years back; *for pay/talk/ pay-as-you-go plans, it's 2 years back *90 days for data usage *150 days for text messages	Dependent on type of phone plan used: # of text messages per month # of incoming/outgoing calls, and length of time, rounded up to nearest minute	A letter of agreement was signed, however there is no formal contract.
France	1 year back	Daily or monthly aggregated data only (depending on the operator) Available: • Voice calls (depending on the operator: incoming/outgoing, TAC code, LAC code, cells (BTS), network, number of units, volume [up and down], number of calls, call duration, first base station) • SMS/MMS (depending on the operator: number [up and down], number of characters or volume, first base station) • Data (depending on the operator: time of connection, TAC code, LAC code, cells (BTS), network, number of units , CRA data, first base station, volume [up and down])	Bouyges Telecom : 22/08/2011 Orange : 28/02/2012 SFR : 03/01/2012

Study centre	Period of historical operator data available *(e.g. 1 year back)*	Data available from network operators	Agreement and/or contracts signed with operators
Germany	2 - 3 years back (depending on operator)	Number of incoming calls, number of successful outgoing calls, total duration of outgoing calls, number of incoming SMS/MMS, number of outgoing SMS/MMS, total traffic data, Type Allocation Code NOTE: these data are available from at least one of the four main operators; varies by operator	September/ October 2010
Greece	1 year back		Not yet
Israel	5 years back	All listed data are aggregated per month • Dates of use • Dates of operator's service for mobile phone number • The number of incoming calls • Total duration of incoming calls • The number of successful outgoing calls • Total duration of outgoing calls • Number of incoming SMS • Number of incoming MMS • Number of outgoing SMS • Number of outgoing MMS • Total data traffic (down/upload) in kilobytes	February 2012
Italy	TIM: 15 months back VODAFONE and WIND: 2 years back H3G: 1 year back	Daily aggregated data only. No TAC, frequency band, first and last base stations.	TIM: October 2012 VODAFONE: July 2011 WIND: April 2012 H3G: December 2012
Japan	Data provided by the participants 3-6 months back	Only the number of outgoing calls, total duration of outgoing calls, total data traffic, and the term of a contract	NA
Korea	By direct index's request to the operators through the website: 4 months back	Available: • Total time of outgoing calls • Number of outgoing SMS/MMS • Total data traffic in kilobytes	NA

Study centre	**Period of historical operator data available *(e.g. 1 year back)***	**Data available from network operators**	**Agreement and/or contracts signed with operators**
Spain	Depending on operator: Orange: 45 days Vodafone: 3 months Telefónica: 1 year	Available: • Telephone Number • Date • Call ID • Incoming or outgoing (Voice, SMS, MMS, Data) • Time of start of call (hh:min) • Duration of call (min) • Type of call : voice , SMS, MMS • If outgoing: attempt or successful • Total data traffic (down and upload) in kb • TAC (type allocation code) • First base station (base station codes) • Frequency Band (UMTS,GSM) NOTE: these data are available from at least one of the operators; differences between operators.	Orange: 12 November 2012 Telefonica: 13 November 2012 Vodafone: 28 November 2012
Taiwan	6 months back	Available: • Dates • The number of successful outgoing calls • Total duration of outgoing calls Available but need to pay 1.5EU/day: • The number of incoming calls • Total duration of incoming calls	NA
The Netherlands	5 years back	All listed data are available, aggregated per month	Vodafone: 2013 T-Mobile and KPN: not yet

WP4 - Exposure assessment

WP leader: [redacted] - HPA

Participant number	1	3	4	**5**	13
Participant short name (WP leader in bold)	CREAL	UU	FT	**HPA**	MONASH
Person-months per participant	0.13	7	4.42	**5.68**	12

ELF Exposure assessment

The work completed during the reporting period relates to the project objectives to provide Gridmaster exposure cartographies (Deliverable 4.4) and an exposure gradient tool kit to assess the ELF and RF exposure of study subjects (Deliverable 4.5), which will be used to assess the risk of brain tumours associated with mobile phone use.

Completion of ELF measurements and modelling

Introduction

One of the main aims of the MOBI-Kids study is to examine possible adverse health effects of mobile phone use in children. This part of the project assesses the ELF magnetic fields produced by the phones, which come from currents in the battery and surrounding phone circuitry. During previous reporting periods a sample of GSM phones was collected and the measurement set-up determined. The focus of this period was on the grouping of phones for modelling of the induced current densities inside phantom heads for the Gridmaster cartographies. The elements of the measurement protocol are illustrated in Figure 3.

Measurements of the ELF magnetic fields from mobile phones

GSM phones were the subject of two dimensional measurement scans and the resulting patterns were used to group the phones and identify representative phones for the modelling of induced current densities in the head. The field patterns for representative phones are shown in Figure 4. Similar measurements were made on DECT phones.

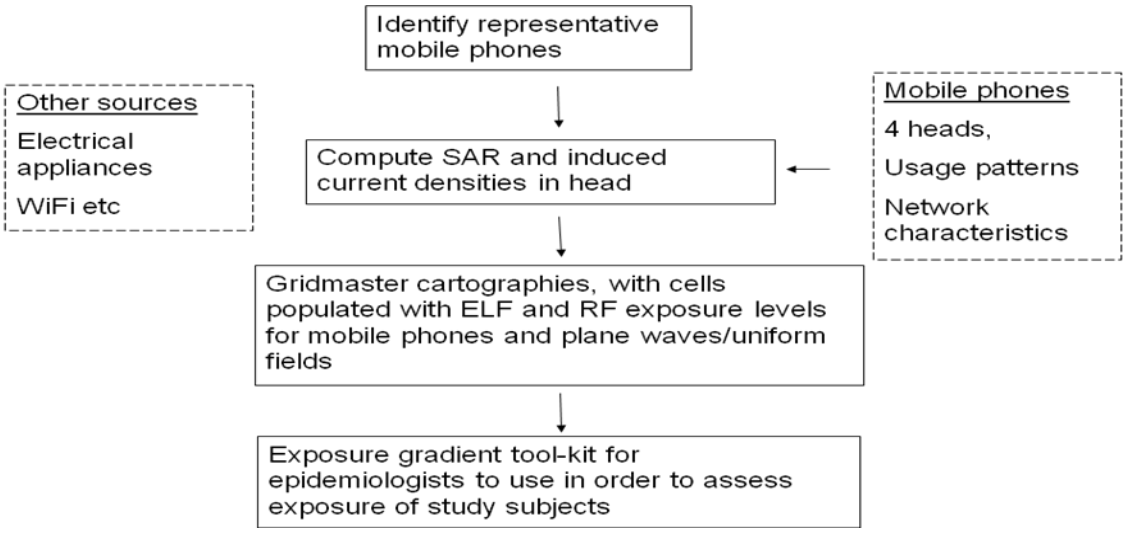


Figure 3: MOBI-Kids – general approach to assessing RF and ELF exposure

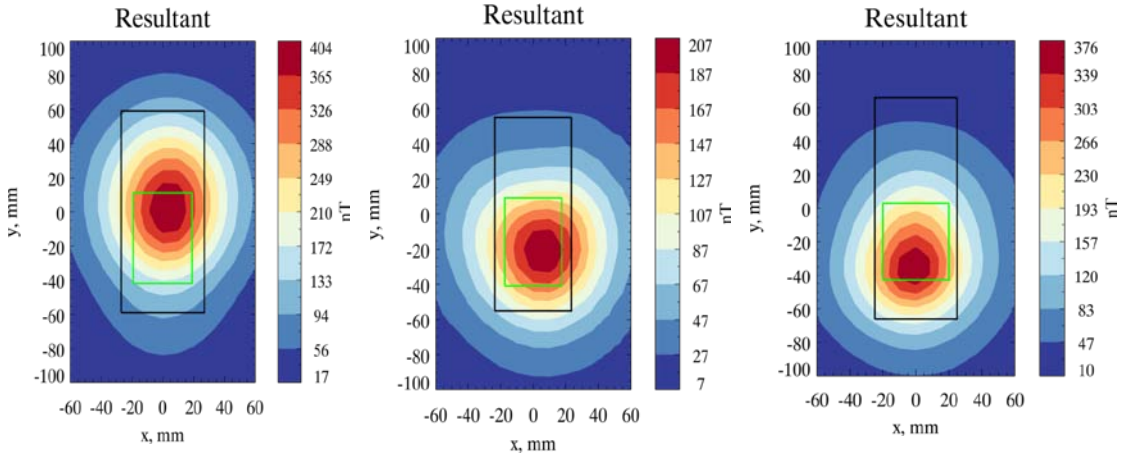


Figure 4: Two dimensional magnetic flux density pattern (217 Hz) for representative phones. The black and green boxes outline the phone and the battery respectively.

Assessing magnetic fields from the mobile phones under HSPA involves investigating the magnetic field waveform characteristics (amplitude, frequency components) under typical, repeatable, conditions. Measurements have also been completed on UMTS and DECT phones and some preliminary tests done using HSPA for voice calls. Preliminary measurements conducted on DECT phones suggest that the ELF magnetic field is likely to be smaller in comparison to the field produced by GSM phones. Magnetic flux density measurements of the DECT phones were considerably lower than those for the GSM phones measured. For example, at its peak the Bz value for the DECT phone was measured at 564 nT, compared to approximately 1800 nT for a representative GSM phone. A 3G base station emulator will be required for the assessment of 3G phones. A US research team is assisting in the assessment of the ELF fields produced by CDMA phones, and the phones used in Japan are also being considered. The fact that new and emerging technologies use less power does not necessarily translate linearly to low magnetic field exposure, as the frequency components of the source need to be considered.

The measurement of sources of magnetic fields from household appliances

A small programme of ELF measurements has been performed on various electrical appliances, including phone and laptop chargers, clock radios and hair dryers. The aim of the measurements is to categorise the magnetic fields around a sample of household

appliances, which children may come into contact with, in order to inform the study questionnaire and exposure algorithm. Some examples of the measurements are shown in Figure 5. The maximum in the vicinity of the appliance is determined by scanning, using a small probe, then broadband measurements are made as a function of distance from the position where the maximum was made. For some appliances it is more appropriate to measure away from the expected direction of use of the appliance, which typically faces the user.

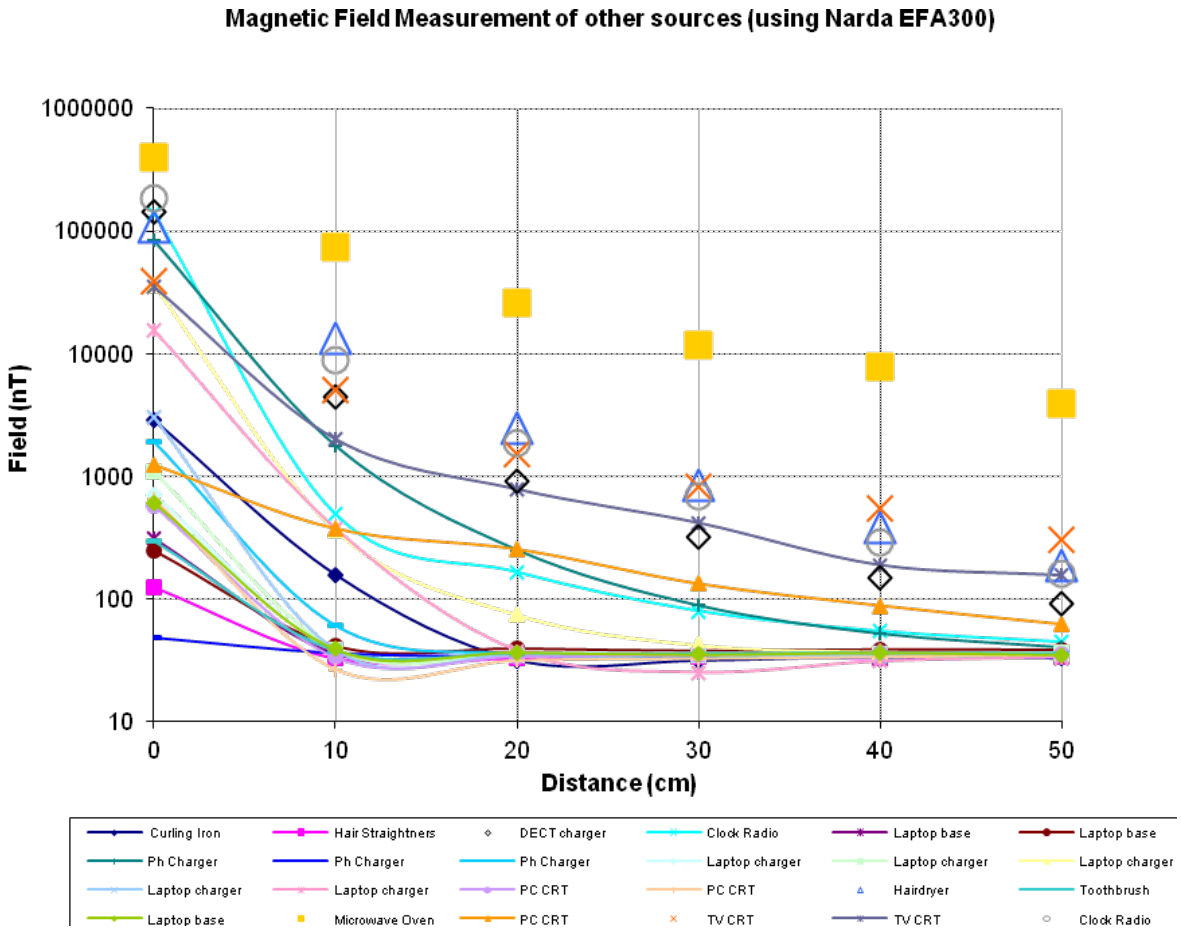


Figure 5: Appliance magnetic fields and fall-off with distance.

Computation of induced current densities inside the head

Computational modelling is used to calculate the induced current densities resulting from the magnetic fields produced by the mobile phones held close to the head. Four ITIS head models (representing 8 yr, 11 yr, 14 yr children and an adult) have been used in this part of the study. The head models are constructed from MRI data at different ages. The original MR images were taken at a resolution of approximately 1x1x1 mm^3 in the axial plane. The original grey-scale images were used to assign different tissue types, in particular skin, bone, cerebrospinal fluid (csf), brain (grey matter) and brain (white matter). Once this editing process is completed, the resulting data were segmented into approximately 10 million voxels in the shape of individual cubes to make up a three dimensional array. Each of these cubes has a tag to identify the tissue type. The dielectric properties are assigned to the tissues using values in the published literature. A 4-Cole-Cole dispersion model was fitted to the data for each tissue type to parameterise the conductivity and permittivity as a function of frequency. These dispersion parameters were used to generate new input data files for the frequencies used in calculations. The

important tissue types here in terms of induced current density are tissues with relatively high conductivity values. These are the cerebrospinal fluid, humour in the eye and the blood. Extremely low conductivities, which usually translate to low values of induced current density, are seen in tissues such as the bone marrow, spinal cord and brain.

A circular loop model was used to simulate the magnetic field produced by each of the representative GSM and DECT phones, the model in effect representing a magnetic field source equivalent to the battery and phone circuitry. The magnetic vector potential and flux density of the circular loop is then calculated using analytical expressions based on Maxwell's equations. The induced current densities inside the head are then modelled using the Scalar Potential Finite Difference method and these were mapped onto a three dimensional computational domain containing the phantom head (Figure 6).

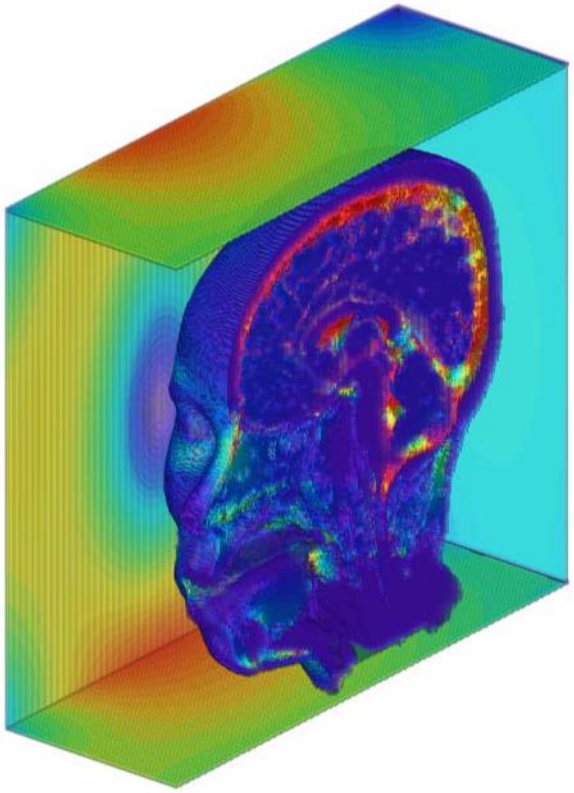


Figure 6: The current density for a vertical slice of the 8 year old model with the phone placed next to the right ear. The colour map is a rainbow spectrum, the highest values in red and the lowest values in violet.

Tests were also completed to assess the effect of battery position on the induced currents in the head. The non-sinusoidal low frequency magnetic fields produced by mobile phones also contain higher frequency components. The treatment of such exposure signals is not trivial; however, these must be taken into account as they will induce comparatively larger currents in the head.

There is also interest in the distribution of induced electric fields in the head and preliminary investigations show that these are quite different from the induced magnetic fields (Figure 7).

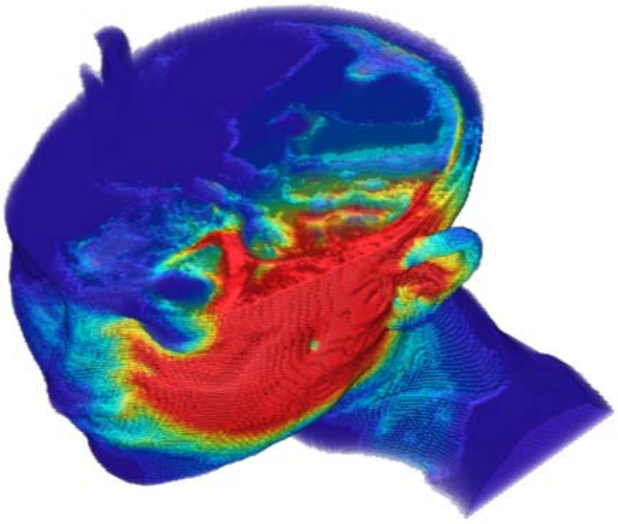


Figure 7: The induced electric field in the head of an 8 year old child model from exposure to the ELF magnetic fields produced by a GSM phone transmitting at 1800 MHz (A cross section through the centre of the head is shown and the highest values are in red and the lowest values in violet)

Input to Gridmaster

The current density values for the four head models have been delivered to the Whist laboratory partners in Paris for onward migration into the Gridmaster software, which is used to demarcate the position of the tumour in the head.

Exposure algorithm

The exposure algorithm is required to enable the epidemiologists to assess ELF and RF exposure of study subjects. The main challenge in both ELF and RF areas is to combine many complex parameters, for instance: phone use; call time; number of calls; number of years use; network characteristics; and the way in which phone is used. An initial discussion document was prepared in 2011; this will be developed over the next reporting period. The approach is expected to follow the INTERPHONE approach in which the exposure is estimated for each phone class in the part of the brain where the tumour is located. The ELF exposure would be considered in terms of induced current density and possibly internal electric field strength.

RF Exposure assessment

Work coordination between France, Japan and Korea

The Whist lab in France is leading the RF exposure assessment, with Japan and Korea – countries that have recently joined Mobi-Kids and have valuable experience and facilities to complement the work planned in France and improve the exposure assessment – undertaking supplementary work on country specific phones and Japan providing some validation of models through measurements on phantoms. In Europe, six representative phones are being used to compute the SAR using four IT'IS head modes: Eartha (8yrs), Billie (11 years), Louis (14 years) and Duke (adult). The SAR will also be calculated for the cheek, tilt and three other positions.

The work conducted during this reporting period has focused on completing all the SAR calculations. In addition, the RF source models and the adult and child head models have

been transferred to Japan and Korea to enable them to model their own representative phones using the same approach. The SAR calculation method (averaging over five different positions of the phone) has also been explained and transferred to Japan and Korea. One reference simulation (one phone model, Duke head model, cheek position of the phone, 3G frequency) has been run in Japan, in Korea and in France in order to coordinate the phone positioning and the FDTD calculations.

A meeting between the French team and the Japanese team is planned for April 2013 in Tokyo.

Progress in simulations

Simulations are being conducted in parallel in France, Japan and Korea, using the same five positions and different country specific phone models. Simulations will be performed using the same four head models in each country, though an additional Japanese child head will also be used in order to evaluate possible differences between Caucasian and Asian heads. Japan is performing calculations for five representative phones and Korea, 11 phones, although some rationalisation may be necessary to meet the project schedule.

Gridmaster completion

The new Gridmaster tool has been modified according to comments received from neuroradiologists from Italy and Germany who tested it. Its use has been found to be fairly easy – with about 2 hours needed to become thoroughly familiar with the software and 5-10 minutes per case needed to review images and mark the tumour location on the grid. The software is ready for use by the neuroradiologists in each country, and software is now being developed to merge the tumour localisation grid with the SAR data and display the whole tumour averaged SAR. Figure 8 shows an example of the Gridmaster.

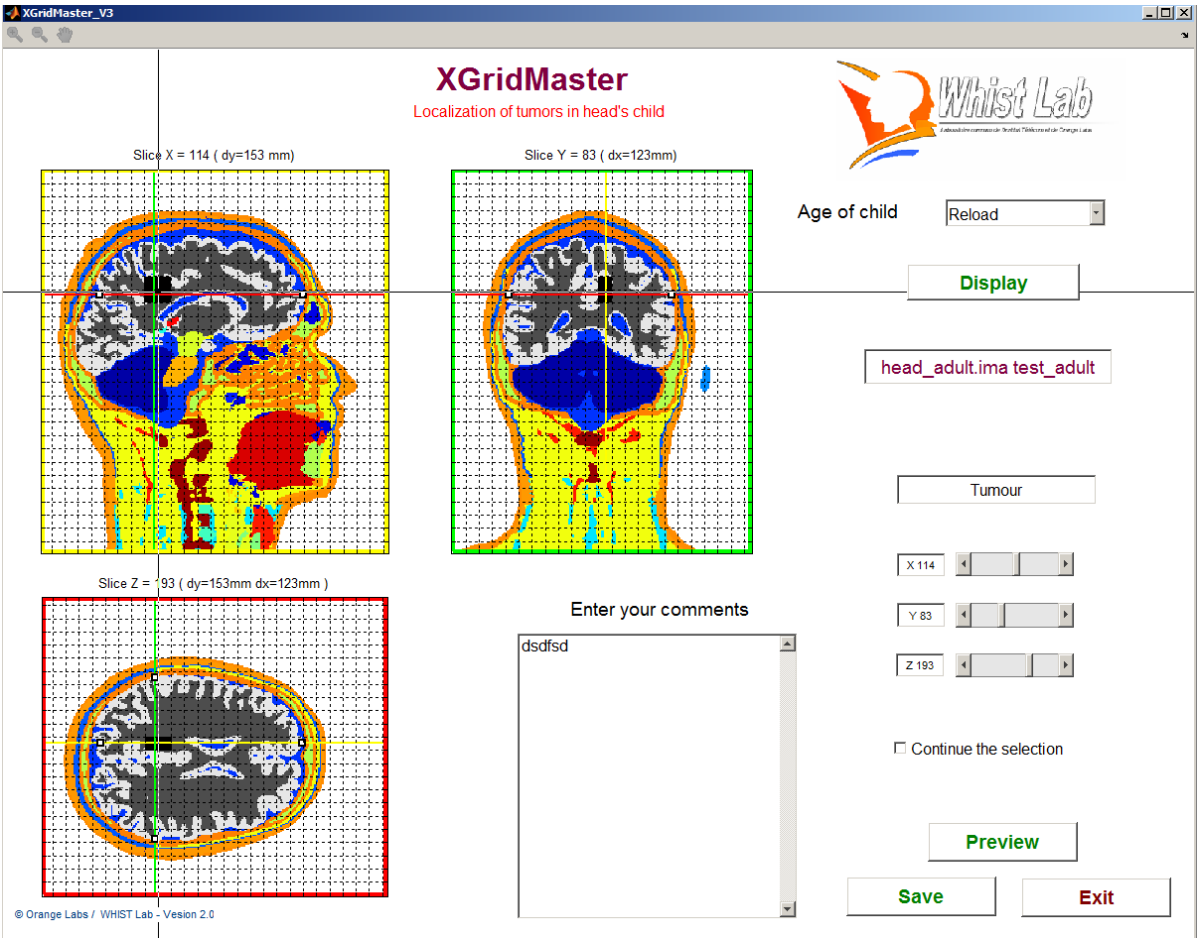
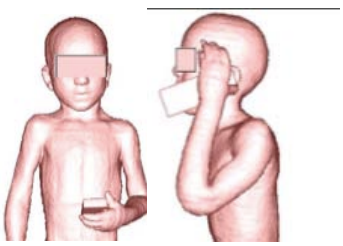


Figure 8: Gridmaster example of an adult head

Comparative analysis of the exposure induced by mobile and RF base station

In order to compare the exposure of a child to mobile phone and to RF base stations SAR calculations have been performed using one numerical voxel whole body child model having a millimeter resolution (Thelonious, 6 years old, 1.17m, 19.3kg, 76 tissues) and two different phone models having different antenna positions. Since the objective was to compare the exposure induced by a mobile phone and a base station the human model was deformed and positioned (see Figure 9) in order to represent a “voice” call and a talk mode “data” configurations. In the “voice” configuration the phone is in cheek position while in the “data” configuration the phone is at about 40 cm from the head as shown in Figure 9.



(a) (b)

Figure 9: Child model in “data” position (a) and in “voice” position (b)

Environmental, residential/school, consumption, and occupational exposure assessment

Environmental exposure

Study centres were asked to fill in an inventory requesting information on available resources for the following subjects: geocoding of residences and their geographical relationship with relevant exposure sources, such as location of mobile phone base stations and power lines; land use maps for agricultural activities such as types of crops grown and pesticide usage; and information from water companies about disinfection by-product levels in drinking water supplies. Such information will be analysed to assess the feasibility of developing metrics for these exposures.

Job history

The quality of the collected job histories was studied (UU and CREAL) and a protocol to improve the quality of the collected information on jobs performed developed (MONASH with input from UU and CREAL). After translation of the provided information on job histories of the index persons, 22% (n=90) of the reported jobs (n=450) were not possible to code using the agreed coding schemes (ISCO68 and ISCO88). The percentages differed considerably between the centres; Japan and Korea in particular had poor quality data (>50% of the jobs were not possible to code). This might be due to translation problems. More background about what will happen to the job information and more specific guidance in the interviewer guidelines has been provided. In the upcoming fieldwork coordinators meeting (May 2013) the new guidance will be evaluated and the quality of the job histories will be re-evaluated.

Deviations in schedule and use of resources

WP4.2 and WP4.3 ELF EMF deliverables are approximately 12 months behind schedule due to equipment delays and because measurement validation tests were longer than expected. The ELF algorithm and final report is expected to be ready by the end of 2013.

For the RF exposure assessment, the simulations are due to be ready for input to Gridmaster by May 2014 and head model experimental validation work will be performed in 2014.

Although quite a bit higher than the originally planned efforts, the used resources are in congruence with the amount of work performed so far.

WP5 – Data analysis & management

WP leader: [redacted] – CREAL

Participant number	**1**	8	11	14
Participant short name (WP leader in bold)	**CREAL**	UNITO	GERTNER INSTITUE	AUCKLAND UNI
Person-months per participant	**16.27**	0.48	1.5	1

Work during this reporting period focused on finalising, translating, and implementing in the field an electronic database using FileMaker Pro for the main and parental questionnaires. Additional databases are included in the electronic application, including:

- a follow-up registry;
- a non-response questionnaire database;
- a mobile phone operators validation study database;
- a clinical questionnaire database; and
- a catalogue of mobile phones.

The complex electronic database was distributed to centres in December 2011 for translation. In FileMaker Pro, translations are done by copying each original presentation (in English), saving each presentation with a different name, and then changing the text in the 'local language' (copied) presentations. The specific translation method varies depending on the type text (i.e. the question itself, multiple-choice responses ('lists'), or a script that changes based on a previous response). Detailed instructions were prepared and updated as necessary to explain to study coordinators how to translate the application, as well as how to add their site-specific responses and issues (e.g., list of hospitals, education responses, etc.). Thorough interviewer instructions for using the electronic database application were also prepared and updated as necessary. In addition, [redacted] and [redacted] had Skype calls with each centre specifically to discuss the electronic application, both its translation and use.

The first centre began using the application in real-time in the field in February 2012, with more centres following in early spring/summer of 2012. Questionnaires that had been administered on paper have been double-entered into the application to ensure high data quality (completed in most centres; second entry pending in a few centres).

A multitude of validation checks were built into the database to verify information is logical as the interview is taking place (e.g., dates cannot be in the future; if a participant reported an exposure, must respond 'yes' to at least one specific exposure; etc). It was deemed to be worth the investment of time and effort (to develop these validations) to ensure the quality and completeness of the interview data (see Figure 10 for an example of a validation check in effect, with a warning message).

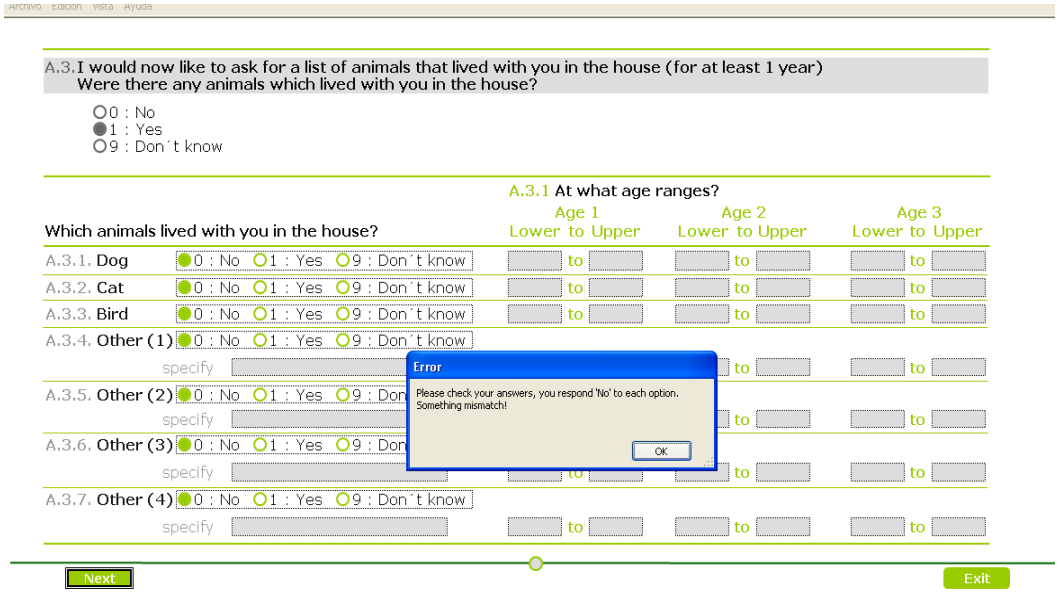


Figure 10: Example of a warning message in MOBI-Kids electronic application (validation check)

After centres began using the application, work began on import/export scripts to transfer data between coordinators and interviewers, and also between local coordinators and CREAL. To export to CREAL, there is a button that separates any identifiable information (e.g., name, address, phone number, residential history, etc). Once the backup file is created, the centre places the file in their country's folder located on CREAL's secure FTP server. If a coordinator needs to transfer the recruitment information of a participant to their interviewer, there is a button to export only the recruitment section. How the file is transferred depends on the specific country, but in these cases, the centres do not use CREAL's FTP server because the personal recruitment information is not allowed to leave the country (by putting it on CREAL's server the information would technically be in Spain).

Once the import/export scripts were working, work began on developing queries for progress reports. Now, centres can generate summaries of their local database (which contains the same fields as the summaries generated by CREAL of the overall database).

Preliminary descriptive analyses have been conducted on the data collected so far, to provide input to WP1 for revised power calculations, WP3 (to assess completeness and validity of information being collected and provide feedback to centres), and WP4 (in assessing priority occupations and exposures as well as main models of mobile phones used).

The development and finalisation of programs for estimating exposure has not yet begun as work is still underway in WP4 to characterise main sources and factors to be taken into account in exposure algorithms.

Deviations in schedule and use of resources

This WP is slightly behind schedule as the final database depended on having final versions of all questionnaires and the development of exposure estimation programmes is dependent on the exposure algorithms being finalised in WP4.

Use of resources in this WP is slightly higher than anticipated because of the complexity of the questionnaire and database and the need to ensure the database is easily usable, translated into all the study languages, incorporates all necessary validation checks, and includes fully functional import/export possibilities as well as data queries.

WP6 - Dissemination

WP leader: [redacted] – LMU

Participant number	1	2	**6**	8	11
Participant short name (WP leader in bold)	CREAL	FIMIM	**LMU**	UNITO	GERTNER INSTITUE
Person-months per participant	1.13	0.1	**8.25**	0.43	0.5

For dissemination, the continuous and main objectives of the project are:

- To design a plan and develop **tools** that **allows for optimal communication** within and outside the project including a **webpage** with a project **wiki** and set-up of a **web conference tool** (Partners 6, 1)
- To **update the scientific community** about the rationale, concept and results of the MOBI-Kids study using these tools (Partners 6, 1, all partners)
- To **raise public awareness** about the current state of science in the discussion on mobile phone exposure and health especially in children and adolescents. To inform the public and patients about MOBI-Kids study and – later on – its results (Partners 6, 1, all partners)
- To **inform the stakeholders, decision makers and experts** in the public health field about the background, design and the results of the study using the communication tools (Partner 6, 1, all partners)

During the study months 31 to 48 no specific deliverables were expected. Therefore we have followed the general aims of this work package (see above).

Tools for communication within and outside the project

(update scientific community, raise public awareness, and inform patients and stakeholders)

To communicate with partners within the project the MOBI-Kids website includes a forum where news are published. Moreover, partners can ask questions or compare notes. Skype is mainly used for communication between partners.

Information for stakeholders is currently limited. Work is underway to prepare information on the topic of the study and the current state of science as well as about the current stage of the study.

Study website

Currently, CREAL is working on a new design for the webpage (Figure 11). In addition to the updated design, a section on “Financial sources” will be added to be transparent with all funding sources (as most centres have local or national funds in addition to those provided by the EU). The “Partners” page will be re-formatted to make it clearer who is doing what work and where (i.e., organised by country, with coordinating centre listed first and then collaborating centres, and centre for exposure assessment, if applicable). LMU is

preparing a concept to create new tools for target specific communication to all stakeholders. Therefore, a survey was started to identify all stakeholders in each country.

The structure of the website is also being redesigned at CREAL to make it more dynamic, allowing for partners to post information as appropriate. Different levels of access will facilitate communication amongst various subcommittees and group; e.g., the Project Board will have a designated area with restricted access to discuss study progress and any concerns. The new structure will also provide a forum for stakeholders to be informed in real time – through feeds – about study progress and about the topic. In addition, centres will be able to translate the pages of their choice, making the website more accessible to participants and interested parties in all of the centres.

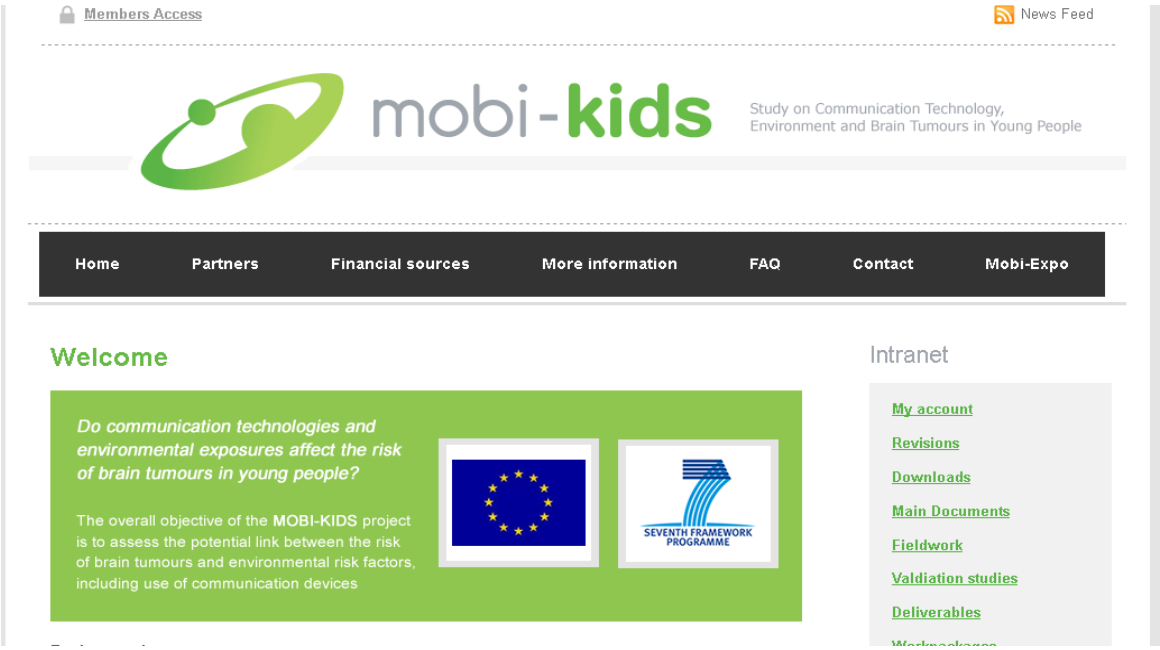


Figure 11: MOBI-Kids updated website design

Systematic review

We are currently preparing a systematic review of the environmental risk factors for brain cancer including mobile phone exposure. The content of this systematic review will be used to inform the scientific community (publication in a peer-reviewed scientific journal), stakeholders and patients/the public (information brochures downloadable from the webpage). A simplified version of the review, translated into lay terms, will be included on the public website under “More information.”

Dissemination

The MOBI-Kids study has been presented at national and international conferences in posters and oral presentations by many of the study partners (see Deliverable 6.9). The study PIs (both at the national and international levels) have given interviews to the press about RF, mobile phones and health and have stressed the importance of MOBI-Kids in bringing new information on the topic.

Deviations in schedule and use of resources

Work in this work package is generally on schedule, though work is needed particularly on the public part of the website to make it more useful for stakeholders.

The used resources are in congruence with the amount of work performed so far.

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WP7 - Project Management

WP leader: [redacted] – CREAL (formerly [redacted] – FIMIM)

Participant number	1	**2**	11
Participant short name (WP leader in bold)	CREAL	**FIMIM**	GERTNER INSTITUE
Person-months per participant	6.39	**0.4**	0.5

A detailed presentation of project management can be found in section 2.3 - Project Management below.

2.3 Project management during the period

Project management in MOBI-Kids is essentially centred on WP7. During this reporting period, management has continued to ensure adequate project progress, comprising:

- Follow-up of activities and monitoring of compliance with the work plan, planned resources and time schedule, promoting as far as possible the synergy between different activities and efficiency throughout, in close co-operation with the Scientific Co-ordination.
- Support to [redacted] in the liaison with the EC Project Officer.
- Submission of project deliverables through the SESAM application and follow-up of milestones achievement.
- Fostering communication within the Consortium. Continuous maintenance of organisation charts, contact lists and a repository of important documents and tools for partners at the MOBI-Kids website (Intranet).
- Meetings organisation, including meetings minutes production, logistics arrangements, and upload of presentations to the Intranet of web site.
- Completion of administrative and financial mid-term report for the second reporting period of the project, including iterations in response to the EC comments, entering data into online SESAM application, resolving issues, etc.
- Financial management: payments calculation and distribution, follow-up of budget consumption, assistance to partners. Preparatory work for administrative and financial periodic reports of the second periodic report.

For all of these tasks, the planned “tandem” leadership structure with the Scientific Coordination has been key to ensure unified project steering and coherence throughout.

The list of meetings held is as follows:

- 7th Exposure Assessment Subcommittee (EASub) Meeting. Barcelona, Spain. 26-27 October 2011.
- 3rd Epidemiology Subcommittee (EpiSub) Meeting. Barcelona, Spain. 26-27 October 2011.

- Project Board Meeting. Barcelona, Spain. 26 October 2011.
- 8th EASub Meeting. Paris, France. 18 April 2012.
- 4th EpiSub Meeting. Paris, France. 18 April 2012.
- Project Board Meeting. Paris, France. 19 April 2012.
- 4th Consortium Meeting. Paris, France.19-20 April 2012.
- 9th EASub Meeting. Barcelona, Spain. 21-22 November 2012.
- 5th EpiSub Meeting. Barcelona, Spain. 22-23 November 2012.
- *(Scheduled: 5th Consortium Meeting. Barcelona, Spain. 7-8 May 2013)*
- *(Scheduled: 10th EASub Meeting. Barcelona, Spain. 6 May 2013)*
- *(Scheduled: 6th EpiSub Meeting. Barcelona, Spain. 6 May 2013)*
- *(Scheduled: Project Board Meeting. Barcelona, Spain. 7 May 2013)*

For all these meetings, hosting has been supported, minutes recorded, and materials have been compiled and placed on the MOBI-Kids website.

Additionally, WP and subcommittee meetings have been held as needed (including teleconferences as appropriate), plus cross-WP meetings on topics of particular interest or when a rapid consensus was needed for convenience.

WP leaders have been given autonomy to organise the work within their respective WPs in the way they think is best. Coordination of WPs has been achieved via Consortium and Project Board meetings, and by direct interaction with [redacted] and [redacted].

The previous organisation in charge of project management, FIMIM, was removed as partner as of Month 38 (30 April 2012), and CREAL absorbed the responsibilities originally allocated to FIMIM. Also regarding partners, Health Protection Agency (HPA) will soon change its name to Public Health England (PHE). In addition, France Telecom (FT) will become Orange as of 1 July 2013.

With respect to payments, one payment has been made to partners in this period. According to the provisions of the Consortium Agreement, a payment was transferred to partners in May 2012, based on the second interim payment received from the Commission after approval of the mid-term (2nd periodic) report and corresponding justifications. In agreement with the PB, the EU Scientific Officer, and the partner, because fieldwork was completely stopped in Austria for over a year, part of the funds for MUV have been retained at CREAL until they can demonstrate that they have been able to recruit at least 15% of the expected study subjects.

Regarding dissemination and use of results, including the project website, the activity of the Consortium has been remarkable. The list of dissemination activities has been introduced in the European Commission online reporting tool, SESAM.

A breakdown of effort by WP and by partner is provided in Table 3 below. The total effort spent in RP3 is approximately 38% (292 person-months) of the total effort planned for the project. This is higher than the first two periods, reflecting the enormous effort spent in setting up and maintaining case and control recruitment, as well as the significant amount of work on exposure assessment. Table 3 reflects the heterogeneity of efforts by partners, in accordance with their role on the project. Centres that have recently begun fieldwork (or

will begin soon) reported fewer person-months, as would be expected. To date, centres have reported 83% of the total planned efforts.

With respect to budget, the reported costs are currently estimated at just over €1.0 million (EC contribution), representing 28% of the total project budget. The total reported budget has risen to approximately €2.6 million, or 74% of the total planned budget. This is lower than the person-months reported as partners have made a great effort to find complementary funding, thus allowing them to continue data collection under the requested extension without funds.

TABLE 3: Reported versus actual efforts by partner and WP																		
	CREAL	FIMIM	UU	FT	HPA	LMU	MUV	UNITO	ARECEA	UOA-SAGR	GERTNER INSTITUTE	UOTTAWA	MONASH	AUCKLAND UNI	**TOTAL Reported RP3**	**TOTAL RP1 + RP2**	***TOTAL Reported efforts***	TOTAL Planned efforts	*% total efforts*
WP1	38.51	0	12.5	0	0	25	4	15.1	30.07	10.84	13.2	20.6	29	6	**204.82**	**210.77**	***415.6***	446	***93%***
WP2	7.75	0	0	0	0	1	0	1	0.2	0	1.35	0	0	1	**12.3**	**45.91**	***58.21***	60	***97%***
WP3	2.59	0	1	0	0	1	0	0.52	1.5	0	1.5	0	0	1	**9.11**	**8.55**	***17.66***	54	***33%***
WP4	0.13	0	7	4.42	5.68	0	0	0	0	0	0	0	12	0	**29.23**	**47.43**	***76.66***	48	***160%***
WP5	16.27	0	0	0	0	0	0	0.48	0	0	1.5	0	0	1	**19.25**	**13.2**	***32.45***	80	***41%***
WP6	1.13	0.1	0	0	0	8.25	0	0.43	0	0	0.5	0	0	0	**10.41**	**16.63**	***27.04***	53	***51%***
WP7	6.39	0.4	0	0	0	0	0	0	0	0	0.5	0	0	0	**7.29**	**12.04**	***19.33***	34	***57%***
TOTAL Reported RP3	**72.77**	**0.5**	**20.5**	**4.42**	**5.68**	**35.25**	**4**	**17.53**	**31.77**	**10.84**	**18.55**	**20.6**	**41**	**9**	**292.41**				
TOTAL RP1+RP2	**101.08**	**16.2**	**26.1**	**6.62**	**29**	**29.8**	**22.75**	**25.08**	**19.8**	**15.4**	**31.3**	**8.4**	**23**	**0**		**354.53**			
TOTAL Reported efforts	**173.9**	**16.7**	**46.6**	**11.08**	**34.68**	**65.05**	**26.8**	**42.65**	**51.57**	**26.24**	**49.85**	**29**	**64**	**9**			***646.94***		
TOTAL Planned efforts	141	38	76	9	21	97	37	49	66	31	61	51	67	31				775	
% total efforts	*123%*	*44%*	*61%*	*123%*	*165%*	*67%*	*72%*	*87%*	*78%*	*85%*	*82%*	*57%*	*96%*	*29%*					*83%*

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