**SEVENTH FRAMEWORK PROGRAMME**
**THE PEOPLE PROGRAMME**

# *Annex I - "Description of Work"**

## PART A:

**Grant agreement for: Industry-Academia Partnerships and Pathways**
**Call identifier: FP7-PEOPLE-2013-IAPP**

**Project acronym: CODEMISUSED**

**Grant agreement no.:** 611736

**Project full title:** Over the Counter Codeine Use, Misuse and Dependence

**Date of approval of Annex I by REA:**

**Project start date: 01/09/2013**

**Duration of the project: 48 months**

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**** This Annex I refers to the 2013 PEOPLE Work Programme** (European Commission C(2012)4561 of 9 July 2012)*

# A.1Project abstract

**Keywords:**
Codeine, Prescribed, Over the Counter, Pharmacy, Opiate Treatment

**Abstract:**
Contemporary research has underscored the need for '*increased pharmaco- vigilance'* around codeine dispensing as the most commonly consumed opiate worldwide. Codeine represents an interesting quandary in terms of its regulated status, with individuals varying in their metabolism of codeine, estimation of safe dosages, and abuse potential. Within user trajectories of codeine use, a variety of sub groups exist in the form of the elderly, youth, parents, recreational, problematic and opiate dependent drug users, and each with their own motives, patterns and outcomes for use. Increases in treatment uptakes relating to codeine dependency and concerns for appropriate design of treatment protocols have been recorded globally. There is a clear need for this unique collaboration to present data on codeine user profiles so as to inform the design of protective mechanisms in the pharmacy profession to track, monitor, support and refer codeine misusers. The research aims to quantify the extent of codeine use, misuse and dependence in three countries (Ireland, United Kingdom and South Africa), with focus on therapeutic and non-therapeutic use, so as to create user profiles of use and abuse and capture individual user, pharmacy, medic and treatment provider perspectives. Data will be used to inform the design of pharmacy based brief interventions and customer monitoring systems, continuing staff training and management of appropriate treatment interventions. A mixed method approach will commence with a meta-analysis and systematic review of literature, which along with national pharmacist, medic and treatment provider surveying, will inform the design and implementation of sweep surveys of individuals purchasing OTC codeine in pharmacies, internet based codeine user focus groups targeting web based sales and use, and interviews with codeine users, mis-users and dependents in each country.

**Updates September 22nd 2013**

Dr Van Hout, Coordinator of the School of Health Sciences Substance Abuse Research Centre at WIT received acceptance for the centre to be registered onto the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) of the European Medicines Agency (EMA).

CODEMISUSED project was accepted onto the Pharmacoepidemiology and Pharmacovigilance (ENCePP) registry of research projects approved by the European Medicines Agency (EMA) for research in the EU.

Professor Michael Evans Brown, Supply reduction and new trends unit, EMCDDA, Lisbon Portugal took a seat on the Expert Advisory Panel.

# PART B:

# B.1 List of participants

| Beneficiary Number * | Beneficiary short name** | Commercial Sector *(Y/N)* | SME *(Y/N)* | Country | Scientist in charge | Month Enter-Exit Project*** |
|---|---|---|---|---|---|---|
| 1 | WIT | N | N | Ireland | Dr Marie Claire Van Hout | M1-M48 |
| 2 | KCL | N | N | UK | Dr Paolo De Luca | M1-M48 |
| 3 | MRC | N | N | South Africa | Dr Charles Parry | M1-M48 |
| 4 | Cara Pharmacy Group | Y | N | Ireland | Padraig McGuiness | M1-M48 |
| 5 | Weldricks Ltd | Y | N | UK | Richard Harris | M1-M48 |
| 6 | The Leading Pharmacy Group | Y | N | South Africa | Gerhard Beukes | M1-M48 |

# B.2S&T Quality

## B.2.1. Objectives of the research programme

Since 2010, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the International Narcotics Control Board (INCB) has expressed concern about the misuse of prescribed and over the counter (OTC) medication and the need for *'increased pharmaco-vigilance'*. Codeine is the most commonly consumed opiate worldwide. Its regulated status varies, and although effects are milder than heroin, abuse potential remains of concern, with physical dependence occurring with regular use over a short period of time. A clearer understanding of the general public's awareness on the potential risks of codeine use, misuse and dependence, and impact of pharmacy dispensing of codeine will ultimately allow professional pharmacy, pharmaceutical, medical, drug and health organisations in the EU to amend and generate new EU standards and guidelines for the prescribing, dispensing and monitoring of codeine and other medicines of misuse.

**Aims of CODEMISUSED**

CODEMISUSED is a collaborative study between academic and pharmacy partners that aims to quantify and explore prescribed, over the counter (OTC) and web retailed codeine use, misuse and dependence in model countries across three regulatory regimes: Ireland (IR), United Kingdom (UK) and South Africa (SA). It aims to carry out a national and international collaborative study to estimate levels of therapeutic and non-therapeutic codeine use, misuse and dependence in partner countries from a variety of sources and perspectives (meta-analysis of literature, prescribed, OTC and web sourced users, pharmacies, general practitioner (GP) and pain management specialists, and addiction treatment providers), and will encourage knowledge, expertise and practice between IR, UK and SA pharmacies around the issue of prescribed, OTC and web based codeine sales, customer intervention, monitoring and tracking, referral and treatment design.

CODEMISUSED is aligned with broader attempts in the pharmacy profession, not only to enhance research capacity, but also give pharmacists the opportunity to become directly involved in the research process supported by CODEMISUSED's team of expert academics in the fields of public health, addiction, pharmacy and internet drug sales. Frontline pharmacy practitioners (chief pharmacists, pharmacists, dispensing technicians and frontline pharmacy staff) who have extensive experience in dispensing codeine products will assist in study designs, will actively participate in fieldwork and disseminate project outputs on return to their national pharmacy chains. Inter-sectorial exchanges will be used to inform, guide, implement and disseminate findings from each proposed work package which commences with a meta-analysis and systematic review of literature on codeine, existing national data sources and codeine sales trends, and are followed by national pharmacist, medical professional and treatment provider surveying, sweep surveys of individuals purchasing OTC and prescribed codeine in pharmacies, internet-based codeine user focus groups targeting web-sourcing, and in-depth face to face interviews with codeine users, mis-users and dependents in each partner country. Innovative practice in the form of accurate customer data systems for tracking and monitoring all forms of codeine misuse, innovative and novel primary health care referral mechanisms, recommendations for prescribing policies and brand packaging, CPD training for pharmacy, health and addiction staff, educational and informational store designs, codeine specific addiction treatment protocols, and brief pharmacy and web based interventions is much needed across the EU.

**The partnership objectives of CODEMISUSED are to:**

- Develop a national, EU and international partnership facilitating research into codeine sales, purchasing habits and patterns of use, misuse and dependence, which will inform customer sales and tracking systems, national pharmacy dispensing practices and customer intervention, the medical profession, primary care referral pathways, codeine specific treatment protocols, public health informatics and drug education campaigns;
- Develop a core inter country collaborative scientific platform for epidemiological information on codeine using a multidisciplinary group of academic and pharmacy experts with a proven track record of collaborative research;

- Promote the outcomes of this collaboration through the dissemination of outputs and inter country templates for quantification of extent of prescribed, OTC and web sourced codeine products sales, and patterns of use, misuse and dependence;
- Promote the outcomes of this collaboration through the dissemination of outputs and contributions to innovation in the form of CPD training for professionals, pharmacy based brief interventions and store design, along with inter country templates for quantification of public health cost of codeine use, misuse and dependence in each country;
- Promote the outcomes of this collaboration through the dissemination of outputs and inter country templates for the development of national policies regarding codeine product sale and dispensing practices, and the design of public health, pharmacy and web based campaigns targeting potential misuse and dependence;
- Enhance and embed the interdisciplinary links, knowledge exchange and the academic-industry collaboration between Waterford Institute of Technology, Ireland (WIT), King's College London, United Kingdom (KCL), South Africa Medical Research Council (MRC), Cara Pharmacy Group, Ireland, Weldricks Ltd, United Kingdom and the Leading Pharmacy Group South Africa;
- Establish a sustainable high quality research cluster capable of attracting funding for future ventures which are intended to include pharmaceutical companies manufacturing and designing codeine based products.

**The scientific objectives of this study are to:**

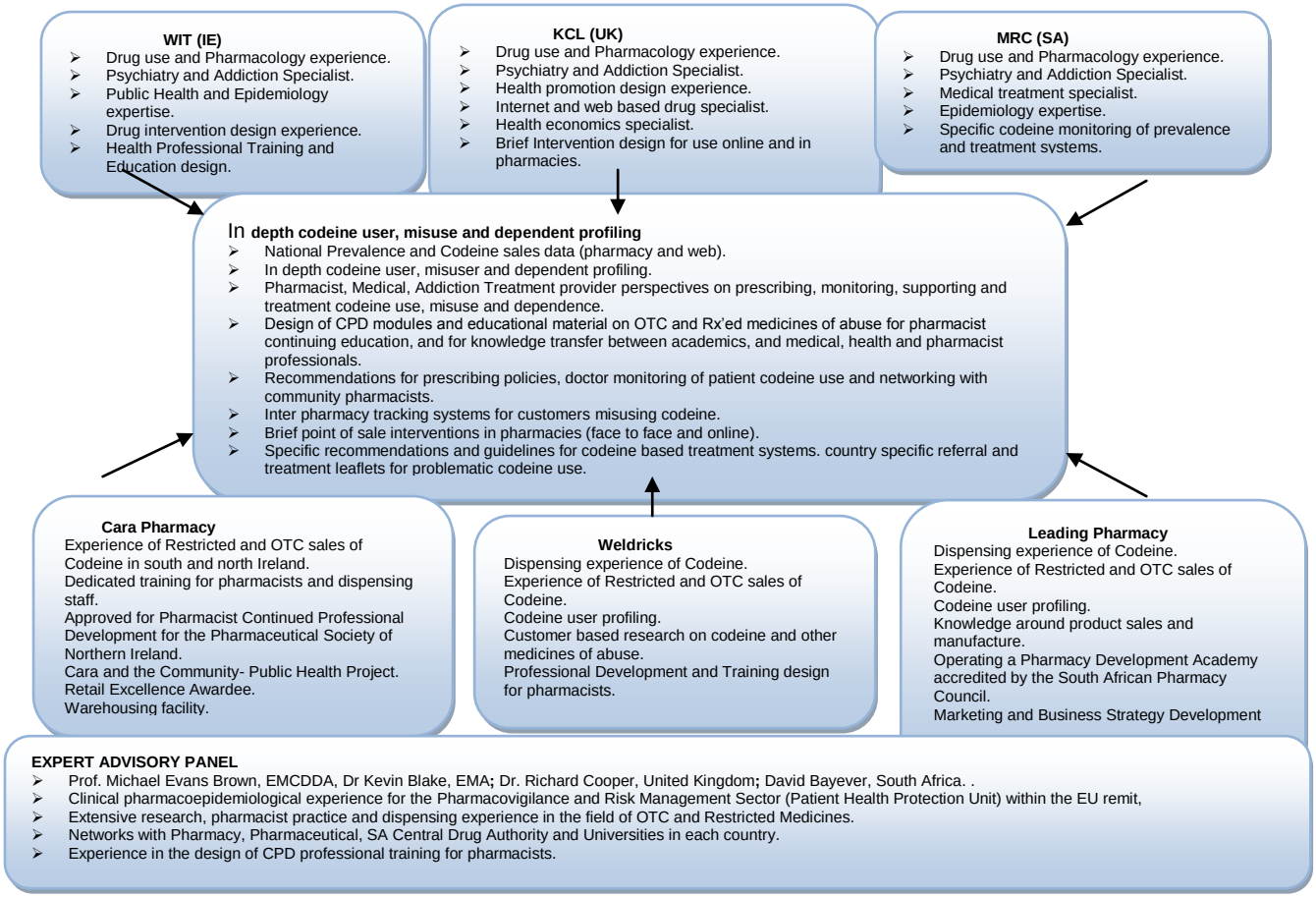
- Conduct a systematic review and meta-analysis of international and national literature on prescribed, OTC and web sourced codeine use, misuse and dependence;
- Develop a comparative profile of codeine product sales trends, and extent of prescribed, OTC and web sourced codeine use, misuse and dependence in Ireland, the UK and South Africa;
- Identify and comparatively analyse the variant trajectories of non-dependant and dependent codeine use to be found amongst the public, referring to purchasing habits and patterns of use, misuse and dependency outcomes via prescribed, OTC and web-based retail sales in Ireland, the UK and South Africa;
- Identify and comparatively analyse the public health impact of therapeutic and non-therapeutic codeine use, misuse and dependence via prescribed, OTC and web-based retail sales in Ireland, the UK and South Africa;
- Identify and comparatively analyse the views of users, medical professionals, general practitioners and pain management experts, pharmacists and addiction treatment providers on codeine use, misuse and dependence and relate these views to the efficacy and impact of current regulation on sales and dispensing practices, displacement between prescribed, OTC and illicitly sourced codeine on the Internet, development of initiatives targeting prescribed, OTC and online brief point of sale interventions, unmet referral and addiction treatment needs and targeted health promotion and in store tactics in Ireland, the UK and South Africa;
- Create a model for use across the EU and South Africa in terms of customer tracking and monitoring systems, designed Internet and pharmacy based customer brief interventions, and continuing education material and session plans for medics, pharmacists, health promotion professionals and treatment providers on Rx'ed and OTC medicines of abuse. This model can be used for other identified medicines of abuse across the EU and South Africa.

## B.2.2. Research methodology and approach

The multi-disciplinary CODEMISUSED team includes members from existing internationally recognised addiction research groups at the School of Health Sciences at Waterford Institute of Technology, Ireland (WIT), the Institute of Psychiatry at King's College London, United Kingdom (KCL), and the Alcohol and Drug Abuse Research Unit at the South African Medical Research Council (MRC) who will work together with experienced Chief Superintendent Pharmacists from each national pharmacy chain, namely; Cara Pharmacy Group (IR), Weldricks Ltd (UK) and the Leading Pharmacy Group (South Africa) whose staff in the form of Designated Pharmacy Researchers will be involved in secondments to academic partners. A Principal Investigator Dr. Marie Claire Van Hout, (WIT) who is an addiction specialist and has consulted for the EMCDDA and UNODC is co-coordinator. Supporting

the aforementioned academic and pharmacy partner expertises, the project will be guided by a specialist and dedicated Expert Advisory Panel represented by Professor Michael Evans Brown, Supply reduction and new trends unit, EMCDDA, Dr Kevin Blake, Clinical Pharmaco-epidemiologist working in the Pharmacovigilance Sector within the Patient Health Protection Unit (European Medicines Agency), Dr Richard Cooper, Pharmacist and Lecturer in Public Health (School of Health and Related Research (ScHARR), University of Sheffield UK), and David Bayever, Director of the Central Drug Authority South Africa (CDA) and Head of Division: Pharmacotherapy and Pharmacy Practice, Research Director: Telemedicine Research and Development, Wits/MRC –NMDIP(University of Witwatersrand Medical School, South Africa).

**Figure 1: Complementarities and Synergies for CODEMISUSED**




The synergy of the academic and pharmacy teams, and exchanges between same, along with the dedicated research and practice based support from the Expert Advisory Panel, will maximise the successful delivery, dissemination, outreach and application of project findings. The team infrastructure intends to act as a central and sustainable resource to provide the European Medicines Agency (EMA) Pharmaco-vigilance and Risk Management Sector, Committee for Medicinal Products for Human Use (CHMP) and Healthcare Professionals' Working Group (HPWG), EMCDDA Pharmaco-vigilant Steering Group and National REITOX Network, INCB, World Health Organisation (WHO), World Trade Organisation (WTO), UNODC and respective national public health, medical, pharmaceutical and pharmacist organisations with a contemporary user profile of codeine and a series of innovative and unique outputs which have the potential to act as model templates for use in the generic area of medicinal misuse and dependence.

The CODEMISUSED project comprises 9 Phases, with each phase organised as a number of work packages. Work packages 2, 3, 4, 5, 6, 7 and 8 will inform the design of interview guides for Work Package 9. Specific risk and contingency plans are presented in each work package in Section B4.

## Phase 1: Project Start-up. Led by WIT (All Partners)

A ***Start Up*** meeting will be hosted by KCL, London in UK in Month 1. This phase will be part of the wider **Work Package 1** on project management and coordination. The management framework supported by the Management, Implementation and Monitoring Groups will provide clear guidance on

how to focus outcomes and facilitate continued close co-operation with all partners in the context of dynamically evolving policies, strategies, research projects and outreach activities. The establishment of quality assurance mechanisms in the context of the management structure will be a measure to reduce the potential risks. The usefulness and uniqueness of knowledge gained will motivate all participants (work package leaders, other participants as well as third parties) to participate fully in the project and minimise risks to collaborative work.An active process will be created to manage the project to ensure communication between and within WPs; ensure that the project proceeds according to plan; ensure the quality of the project's deliverables through the development of quality assurance procedures; ensure coordinated communication between all beneficiaries; monitor the progress of work on the project and take corrective measures where appropriate; manage the funding of the project; report regularly as required to the European Commission; and organize and co-ordinate project reviews as required.

**Phase 2: Systematic Review of Literature. Led by WIT (All Partners)**

**Work Package 2** will carefully review and describe the nature of data relating to codeine in each country. An extensive literature search of EMA, EMCDDA, UNOCD, INCB, WHO documents, resources, reports, scientific papers and books offering description and analyses of national legislations, recent experiences in prevention, treatment and harm reduction and trends in the area of codeine will be conducted, along with governmental consultation for national data. A meta-analysis will be conducted on the available data relating to codeine prevalence and treatment.

**Phase 3: An emailed web based survey in each model country examining the perspectives of Medical professionals on codeine prescribing, use, misuse and dependence, and potential drug displacement patterns between prescribed, OTC and web sourced codeine use. Led by WIT (All Partners)**

**Work Package 3** examines the perspectives of a nationally representative sample of medical professionals in each participating country and will be analysed using a web based survey which investigates levels of and public health impact of therapeutic and non-therapeutic prescribed, OTC and web sourced codeine use, misuse and dependence, drug displacement patterns between prescribed and OTC/web sourced codeine, pain management strategies, preventative and referral tactics for use via the pharmacist, online and in the community, perspectives on the development of specific treatment policies and referral pathways, and ideas around CPD content and networking between medics and pharmacies in each model country.

**Phase 4: An emailed web based survey in each model country examining the perspectives of Pharmacy staff on extent of therapeutic and non-therapeutic use, misuse and dependence on prescribed, OTC and web sourced codeine products. Led by MRC (All Partners)**

**Work Package 4** examines the perspectives of a nationally representative sample of pharmacists, dispensing technicians and frontline staff in each model country and will be analysed using a web based survey which investigates levels and public health impact of prescribed, OTC and web purchased codeine use, misuse and dependence, alongside their perspectives on pharmacy based point of sale brief interventions, customer monitoring, referral pathways, addiction treatment guidelines for codeine, gaps in health service provision, potential health campaigns, and continuing networking between medics and pharmacists to address potential displacement toward customer dependency on codeine.

**Phase 5: An emailed web based survey examining the perspectives of Addiction Treatment Provider's in each model country on current regulation of codeine and its impact on extent of therapeutic and non-therapeutic codeine use, misuse and dependence. Led by KCL (All Partners)**

**Work Package 5** examines the perspectives of a nationally representative sample of addiction treatment providers in each model country and will be analysed using a web based survey which investigates levels of codeine dependence, as primary, secondary and tertiary drug of dependence, perspectives on appropriate treatment for this opiate drug as distinguished from the traditional substitution therapy, confounding factors such as pain management impacting on treatment outcome, and potential in/out patient psycho-social interventions.

**Phase 6: A random sweep survey of Customers purchasing prescribed and OTC codeine based products at pharmacy point of sale to capture the variant trajectories of therapeutic and non-therapeutic codeine based product purchasing and use amongst the public in each model country. Led by MRC (All Partners)**

**Work Package 6** examines customer attitudes towards the therapeutic and non-therapeutic use of prescribed and OTC codeine products, with analysis of self-reported prescribed, OTC and web sourced

codeine purchasing, reasons for use of codeine based products, self-reported patterns of purchasing and use, codeine use outcomes over time, any poly medicine use, side effects of use and problematic use as stratified in relation to age, gender, ethnicity, education and income.

**Phase 7: An Internet Survey of individuals purchasing codeine based products from web based outlets serving each model country to capture the variant trajectories of nondependent and dependent codeine based product use amongst the public. Led by KCL**

**Work Package 7** consists of an Internet monitoring exercise conducted by the recruited researcher to KCL. The aim will be to track users' endorsement and to estimate relative popularity of codeine based products (incl. patterns of use, preferred route of administration, dose, and combination with other products/substances); to review and build a profile of effects (short and long term effects), side effects, risks of misuse/dependence of reported recreational use for each product; explore/assess the relative diffusion of codeine-containing products in *"non-registered*" online pharmacies and other online shops.

**Phase 8: Qualitative interviews with Codeine Users, problematic users and those in addiction treatment in each model country. Led by WIT (All Partners)**

**Work Package 8** will undertake a series of semi structured in depth interviews with codeine users to capture illustrative data pertaining to choices and decision making to use codeine (prescribed or otherwise), experience of sporadic and continued codeine use, reinforcers for use, perceptions of risk and abuse potential, harm reduction practices, use of other drugs or medicines, adverse health consequences, favoured route of administration, non-therapeutic use and extraction of codeine from combination products, opinions around medical prescribing, pharmacy dispensing and web based retail, and perspectives on treatment referral, uptake and outcomes. Recruitment of users will occur via referral from Work Packages 4, 5, 6 and 7, and via the online forums *'Codeine Free'* and *'Overcount'*.

**Phase 9. Innovation. Led by KCL (All Partners)**

**Work Package 9** will utilise the outputs garnered in Work Packages 2-8, along with a series of focus groups with Chief Superintendent Pharmacists, Pharmacists, Dispensing Technicians and Front Line Pharmacy staff in each country. It aims to create innovative outputs for use across the EU in the form of CPD modules for knowledge transfer between academics, and medical, health and pharmacist professionals; a series of recommendations for prescribing policies and brand packaging, medical monitoring of patient codeine use and networking with pharmacists; design of brief point of sale interventions in pharmacies (face to face and online), development of inter pharmacy tracking systems for customers misusing codeine; design of educational informational signage and other in store design issues, a series of specific recommendations and guidelines for codeine based treatment systems, country specific referral and treatment leaflets for problematic codeine use, and educational material on OTC and Rx'ed medicines of abuse for pharmacist continuing education.

**Phase 10: Dissemination. Led by WIT (All Partners)**

Recommendations identified in **Work Packages 1-9** will be disseminated via the Dedicated CODEMISUSED Project website as public health portal as short technical reports and factsheets, via project workshops, seminars, national and international conferences at various stages, and via the publication of national EU and international reports and scientific papers. Scientific papers and reports will be forwarded to the EMA Pharmaco-vigilance and Risk Management Sector, EMA-CHMP, EMA-HPWG, EGPRN and EMCDDA for dissemination via the REITOX Network of National Focal Points, the Pharmaco Vigilant Steering Group and for consideration in '*Special Issue'* monographs, and other relevant international organisations (INCB, UNODC, WHO). Findings will also be sent to each countries' Proprietary or Pharmaceutical Associations so as to boost involvement with product manufacturers. Marie Curie Ambassadors (both academics and pharmacy secondees) visiting educational institutions will deliver short public seminars and training for students, workshops, conference seminars, podcasts via the CODEMISUSED website, e-Newsletters and E-bulletins and national media coverage. The **Work Packages 10** '*Networking Support'*, **11***'Liaising, co-ordinating and linking to other European projects and programmes'* and **12**'*Sustainability'* will be achieved through partner and Expert Advisory Panel networking, partnering and consultation with a wider network of medical, addiction and pharmacist experts in the form of organisation and attendance of meetings, workshops, seminars and conferences for industry, government, academic, medical, pharmacy and addiction treatment stakeholders in each country.

# B.3Transfer of Knowledge

## B.3.1. Quality and Importance of the Transfer of Knowledge programme

The emerging use of codeine based products internationally makes CODEMISUSED a unique and timely project designed to inform the Pharmaco-vigilance and Risk Management Sector (Patient Health Protection Unit, EMA), EMA-CHMP, EMA-HCWG, EGPRN, EMCDDA, WHO, INCB and UNODC. CODEMISUSED will facilitate the advancement of research, and contribute to continued policy maker dialogue around regulation OTC and Rx'ed medicines of abuse, inform continued professional development of under- and post-graduate student education, along with professional pharmacy, medical, health professional and addiction counsellor CPD training in each country, and provide model templates for prescribing policies and brand packaging, the design of improved pharmacy dispensing practices, customer brief point of sale interventions (pharmacy and online), customer monitoring and tracking systems, signage and store design, referral pathways for those experiencing dependence, codeine specific treatment modalities and design of specific CPD training for medics, pharmacy staff, health and addiction treatment providers. The long term outcome strategy is to develop an expert addiction, medical, health and pharmacy research cluster with high-quality outputs and strategic involvement with academic institutions and industry.

The transfer of knowledge and practice based skills will be facilitated and supported by the Expert Advisory Panel who represent the EMA, EMCDDA and each model country, and who combined have a significant track record in pharmacy practice, regulation of medicines and codeine research. Due to the synergies in the resulting collaboration, it will be possible for CODEMISUSED to garner:

- Model country and internet specific customer profiles for pharmacy and web based sales;
- User profiles encompassing a range of therapeutic and non-therapeutic uses;
- Pharmacist, medical and treatment provider perspectives relating to regulation, prescribing practices and monitoring of customer demand and harms;
- Codeine user experiences and displacement patterns between prescribed, OTC, web and other medicines;
- Develop a unified pharmacy product tracking system for use in codeine and other medicines, point of sale brief interventions, store and signage designs, specific codeine treatment protocols and CPD training materials for use across the EU and South Africa.

CODEMISUSED seeks to foster dynamic collaborative pathways between WIT (Ireland), KCL (UK), MRC (South Africa), and three large national pharmacy chains (Cara Pharmacy Group, Ireland, Weldricks Ltd UK and the Leading Pharmacy Group, South Africa) in a three-year study, with great potential for increased knowledge-sharing around therapeutic and non-therapeutic codeine use, misuse and dependence through pharmacy and academic partnering. It is invaluable for CODEMISUSED to have such a collaboration of research, practice based and expert synergies in the field of medicine abuse and pharmacy practice. The mixture of researchers in this project is chosen to reflect the expertise available in all of the host organizations in order to exploit knowledge transfer as it relates to pharmacy practice, addiction, public health, internet drug monitoring, medical prescribing and treatment, health promotion and brief interventions. WIT, KCL and MRC will benefit especially from collaboration with pharmacy partners Cara Pharmacy Ltd, Weldricks Ltd, and the Leading Pharmacy Group who have expert perspectives on prescribed and OTC codeine dispensing, customer monitoring, CPD training, educational informational signage and store design, product development and prior experience of research in this area. WIT will benefit enormously from partnering with KCL and the MRC due to their specialism in internet based drugs research and clinical expertise in codeine dependence and epidemiology respectively.

Mobility and knowledge transfer will be a two-way process between academia and the pharmacy chains during each work package and is optimised via the Dedicated CODEMISUSED Project website, online focus groups hosted by this website, Skype conference calls, team workshops and seminars, podcasts, e-bulletins, public information sessions, involvement of a wider network of key experts as CODEMISUSED progresses, medical, health promotion and pharmacy CPD training sessions, involvement of national pharmaceutical and proprietary associations, and national, international and WIT hosted conferences. CODEMISUSED benefits greatly from the development of

an innovative research culture within the pharmacy partners, both from active participation of Superintendent Pharmacists and Designated Pharmacy Researchers during the project's lifespan and the formation of strong links with academia. Superintendent Pharmacists and Designated Pharmacy Researchers will partake in medium and short term secondments (intra and international) so as to be actively involved in research fieldwork in all three countries, alongside the designated secondee. On reintegration in their respective pharmacy chains these secondees are responsible for in house and organisation wide dissemination of findings via staff training, CPD workshops, reports and factsheets. This work will help pharmacy partners develop good practice with regards to point of sale brief interventions around prescribed and OTC codeine, the monitoring of customer behaviours and product sales, and store or product designs.

## B.3.2. Role of exchanged/recruited staff within the ToK programme

CODEMISUSED is based on the cross-fertilisation of ideas and knowledge between academic leaders in the field, and expert pharmacy practitioners, by focusing in on the key strengths of the academic and pharmacy partners involved, and active involvement of pharmacy staff in the research process and dissemination of findings on return to national pharmacy chains in model countries. Partners will contribute to the emerging critical mass of evidence based knowledge in the field of medication abuse and the global evidence base on codeine consumption patterns and associated harms.

**Outline of Secondments**

The project consists of long, medium and short term secondments. All partners and members of the Expert Advisory Panel will advise and monitor their progress throughout the designated work packages. See **Table below** for outline of secondments and chosen mix of researchers in terms of their experience.

| Secondee | From | To | Type | Duration (Months) | International (Months) | Intra-national (Months) |
|---|---|---|---|---|---|---|
| (1) Dr Marie Claire Van Hout (MER) | WIT | The Leading Pharmacy | International | 4 | 4 | 0 |
| | | Cara Pharmacy | Intra-national | 18 | 0 | 18 |
| (2) Professor John Wells (MER) | WIT | The Leading Pharmacy | International | 2 | 2 | 0 |
| (3) Professor Ian Norman (MER) | KCL | The Leading Pharmacy | International | 2 | 2 | 0 |
| | KCL | Cara Pharmacy | International | 2 | 2 | 0 |
| (4) Dr Paolo Deluca (MER) | KCL | Cara Pharmacy | International | 2 | 2 | 0 |
| | | The Leading Pharmacy | International | 2 | 2 | 0 |
| (5) Dr Andreas Kimergard (MER) | KCL | Cara Pharmacy | International | 2 | 2 | 0 |
| | | The Leading Pharmacy | International | 2 | 2 | 0 |
| (6) Professor Charles Parry (MER) | MRC | The Leading Pharmacy | Intra-national | 2 | 0 | 2 |
| | | Weldricks | International | 2 | 2 | 0 |
| | | Cara Pharmacy | International | 2 | 2 | 0 |
| (7) Tara Carney (MER) | MRC | The Leading Pharmacy | Intra-national | 2 | 0 | 2 |
| | | Cara Pharmacy | International | 2 | 2 | 0 |
| | | Weldricks | International | 2 | 2 | 0 |
| (8) Eileen Rich (MER) | MRC | Weldricks | International | 4 | 4 | 0 |
| | | Cara Pharmacy | International | 4 | 4 | 0 |
| | | The Leading Pharmacy | Intra-national | 9 | 0 | 9 |
| (9) Siphokazi Dada (ER) | MRC | The Leading Pharmacy | Intra-national | 9 | 0 | 9 |
| | | Weldricks | International | 4 | 4 | 0 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Cara Pharmacy | International | 4 | 4 | 0 |
| (10) Michelle Foley (MER) | WIT | Weldricks | International | 21 | 21 | 0 |
| (11) Dr Michael Bergin (MER) | WIT | The Leading Pharmacy | International | 2 | 2 | 0 |
| (12) Padraig McGuinness (Early Stage Researcher) | Cara | KCL | International | 2 | 2 | 0 |
| | | MRC | International | 2 | 2 | 0 |
| | | WIT | Intra-national | 5 | 0 | 5 |
| (13) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | KCL | International | 2 | 2 | 0 |
| (14) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | KCL | International | 3 | 3 | 0 |
| (15) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | KCL | International | 2 | 2 | 0 |
| (16) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | KCL | International | 2 | 2 | 0 |
| (17) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | MRC | International | 2 | 2 | 0 |
| (18) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | MRC | International | 3 | 3 | 0 |
| (19) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | MRC | International | 2 | 2 | 0 |
| (20) Designated Pharmacy Researcher (Early Stage Researcher) | Cara | MRC | International | 2 | 2 | 0 |
| (21) Richard Harris (Early Stage Researcher) | Weldricks | KCL | Intra-national | 2 | 0 | 2 |
| | | WIT | International | 2 | 2 | 0 |
| | | MRC | International | 2 | 2 | 0 |
| (22) Anna Rapca (Early Stage Researcher) | Weldricks | KCL | Intra-national | 9 | 0 | 9 |
| | | WIT | International | 3 | 3 | 0 |
| (23) Tendai Chisambara (Early Stage Researcher) | | MRC | International | 9 | 9 | 0 |
| (24) Gerhard Beukes (Early Stage Researcher) | The Leading Pharmacy | WIT | International | 2 | 2 | 0 |
| (25) Christine Mburu (Early Stage Researcher) | The Leading Pharmacy | KCL | International | 5 1/2 | 5 1/2 | 0 |
| | | WIT | International | 4 1/2 | 4 1/2 | 0 |
| (26) Selina Seima (Early Stage Researcher) | The Leading Pharmacy | KCL | International | 5 1/2 | 5 1/2 | 0 |
| | | WIT | International | 4 1/2 | 4 1/2 | 0 |
| (27) Soekie Senekal (Early Stage Researcher) | The Leading Pharmacy | MRC | Intra-national | 5 | 0 | 5 |

## Justification of Long Term Secondments

The long secondments of WIT secondees will involve significant transfer of knowledge between academic and pharmacy partners. These long secondees will lead in the transfer of academic research expertise and knowledge to the pharmacy group at each of the critical stages relevant to all work packages. This expertise includes guidance on sampling and representation of the population to reduce bias, improve reliability and generalisibility of the results, methods for accessing the population for research data collection, survey instrument design and development, including piloting of the survey instrument, data collection methods and data analysis techniques. It will also transfer knowledge and expertise in qualitative data collection and interpretation. Considering the nature of these national studies, there are a considerable number of pharmacy locations to access where training of pharmacy staff will be facilitated by the academic secondees. The transfer of pharmacy based practice knowledge back to WIT will be related to clinical and OTC medication management including monitoring and reviewing of codeine based drugs, patient compliance and customer relations. Pharmacy partners during these long secondments will inform WIT secondees around the delivery of customer education, monitoring of problematic use, medical and treatment referrals, conflict management relating to demanding customers, and potential for brief interventions. Equally, the transfer of knowledge from pharmacy to academic partners throughout the long secondments will be vital to inform and develop survey instrument design, interview guides and subsequent data collection methods.

**Long Term Secondment 1 (international):** Michelle Foley (WIT) goes from WIT to Weldricks Pharmacy Ltd, UK for a period of 21 months. Michelle is experienced in health epidemiology and health statistics, with a post graduate Medical Science and Chemistry background. This secondment will allow the transfer of knowledge of the realities of UK customer access to pharmacies, medical and pain management prescribing practices and patient experiences, pharmacist, addiction treatment provider and user perspectives back to WIT, KCL and MRC which currently has little knowledge of UK pharmacy based practice, UK customer and user profiles or web specific trends in the therapeutic and non-therapeutic use of codeine. She will be assisted by the Superintendent Pharmacist and Designated Pharmacy Researcher from Weldricks, with input from secondees from Cara Pharmacy Pharmacy Manager and Pharmacists, and Leading Superintendent Pharmacist and Designated Pharmacy Researchers. Weldricks will draw on existing research experiences in the area and will guide the research process to inform the design of brief point of sale interventions as one of the innovative outputs in Work Package 9.

**Long Term Secondment 2 (intranational) (**Dr Marie Claire Van Hout (WIT) is an experienced researcher (MER) and goes from WIT to Cara Pharmacy Ireland for a period of 18 months which is split into 8 and 10 months. This secondment will allow the transfer of knowledge of the realities of Irish customer access to pharmacies, medical and pain management prescribing practices and patient experiences, pharmacist, addiction treatment provider and user perspectives, and online user sourcing and purchasing habits back to WIT, KCL and MRC which currently has little knowledge of Irish pharmacy based practice, Irish customer and user profiles or web specific trends in the therapeutic and non-therapeutic use of codeine. The Cara Pharmacy group is an award winning group (Retail Excellence) of 16 companies comprising 13 pharmacies, a health and beauty web shop, two Cara Home stores and a wholesale warehouse business. They have strong links with the community through their foundation "Cara and the Community" places their pharmacists in the heart of Irish communities giving training and advice to local communities on health issues. They also assess the Pharmacist Continued Professional Development for the Pharmaceutical Society of Northern Ireland. She will be assisted by the Pharmacy Manager, Superintendent Pharmacists and Designated Pharmacy Researchers from Cara Pharmacy, with input from Weldricks and Leading Superintendent Pharmacist and Designated Pharmacy Researchers who develop research tools, conduct fieldwork and analyse data alongside her.

**Medium Term Secondments (intranational):** The medium term secondments of 9 months (x2) reflect the transfer of knowledge achieved in the concurrent long term secondments of 21 and 18 months respectively. Eileen Rich (MER) and Siphokazi Dada (ER) experienced researchers from the MRC go to The Leading Pharmacy, South Africa for a period of 9 months (each). These secondments will allow the transfer of knowledge of the realities of South Africa customer access to pharmacies, medical and pain management prescribing practices and patient experiences, pharmacist, addiction treatment provider and user perspectives, and online user sourcing and purchasing habits back to WIT, KCL and

MRC which currently have little knowledge of South African pharmacy based practice, customer and user profiles or web specific trends in the therapeutic and non-therapeutic use of codeine. They will be assisted by the Superintendent Pharmacist and Designated Pharmacy Researchers from Leading, with input from the Cara Pharmacy and Weldricks Superintendent Pharmacist and Designated Pharmacy Researchers. Leading Pharmacy will inform the design of CPD training initiatives and store /educational informational signage designs as one of the innovative outputs in Work Package 9. In addition, the Designated Pharmacy Researcher from Cara Pharmacy will second to MRC and KCL for a period of 11 months respectively to provide expert industry guidance to the national research WPs.

**Short Term Secondments: (inter and intra national)** A number of important secondments of academic staff with specific research expertise to Cara Pharmacy, Weldricks and Leading Pharmacy and secondments of Superintendent Pharmacists and Designated Pharmacy Researchers from same to partner academic sites for participation in the work packages will take place throughout the duration of the project for periods of 2-5 months. These secondments will be supported by the Expert Advisory Panel and occur at the start of each work package to discuss research design, as part of fieldwork, on completion of data collection, for data analysis and on completion to reflect on experiences and processes, and discuss outputs generated, and dissemination tactics. All participants will liaise and network with each other during these secondments, which will strengthen existing academic-pharmacy networks while establishing new contacts in each participating country. Some shorter visits by the Coordinator, Work Package Leads, Management Teams and Expert Advisory Panel members will take place prior to commencement of work packages, to review progress on completion of each work package, and on culmination of phases. These visits will evaluate data, resolve problems, design outputs, discuss dissemination tactics and provide overall guidance of CODEMISUSED. In addition to the outlined long, medium and short secondments of staff, it is proposed to recruit one Experienced Researcher (ER) for a period of 18 months for hosting in the United Kingdom (KCL).This recruited researcher will have significant experience in the area of Internet based drugs research and will fill gaps in the expertise portfolio of the partnerships, so as to knit together the various aspects of the project throughout its duration. As part of their work on the project, he/she will visit Cara and Leading pharmacies for periods of 2 months respectively after 18 months at KCL thereby allowing for further knowledge transfer, exchange of ideas and perspectives between partners.

**Distinct special measures that will be taken to transfer knowledge between the host institutions.**

It is envisaged that seconded and recruited staff (in the form of academic researchers, Superintendent Pharmacists and Designated Pharmacy Researchers) along with the Expert Advisory Panel and work package Leads, will work together on each work package so that research activities are conducted concurrently in each country, and therefore optimise on knowledge transfer and learning between academic and pharmacy partners. This will facilitate open dialogue between academic and pharmacy secondees and hosts in the design, recruitment and access, implementation, milestones and analysis of CODEMISUSED. A list of questions covering different topics will be prepared and given to secondees on commencement of the work, who will over time prepare answers to these questions based on their observations during each work package and give detail on discussions with local colleagues during the secondment. At the end of each work package, and on completion of the project, the secondee will reflect and present subsequent experiential findings, for example differences between procedures in different countries, differences in client profiles, ideas, procedures and initiatives that they will take back to their own country/sector and suggestions for the hosting institution. CODEMISUSED will operate in a holistic and inclusive manner between all partners and the Expert Advisory Panel, generate extensive academic and practice based dialogue and reflection, so as to ensure critical decision making from all sides throughout the lifespan of the project. Seconded and recruited staff will be supervised and mentored by a senior coordinating member in the host organisation, and will receive a specific training plan, listing of fieldwork tasks, secondment and reintegration plan. Meetings will be held in WIT, KCL and MRC and via Skype conferencing with all partners. Short secondments will be managed by a designated agenda and programme of work, with the host organisation providing Skype video conferencing facilities to allow all partners participate in meetings taking place during these short visits. The primary role of short secondments will be the assessment of results and processes involved in the preceding phase of work, brainstorming sessions to decide how results will be disseminated and used to benefit and inform the next phase of work, and a comprehensive consideration of all elements in the

form of pharmacy based and researcher expertise necessary for the proceeding phase of work. Regular progress meetings to keep abreast of developments and input ideas/potential solutions will be held between research coordinators and pharmacy leads in each country, with minutes disseminated to the wider group of participants. In addition to support and facilitation from the Expert Advisory Panel, collaboration with other experts in the area of codeine, *'legal highs'*, opiate dependence, medics and pain management experts, pharmacy practitioners, health professionals and addiction treatment providers will be sought and developed throughout the project, so as to optimise on the study outcomes, and disseminate the relevance of outcomes for other countries experiencing misuse of medicines.

**Details of the in-built return mechanisms that will ensure efficient transfer of knowledge back into the organisation of origin of the seconded staff.**

It is vital that WIT and collaborating partners remain abreast of emerging drug trends in the public health sphere, so as to inform future academics, prescribers, pharmacy practitioners, treatment providers and health professionals. All secondees are permanent or long term employees, and will return to their organisations on completion of the work. Long and medium term secondments of 9-21 months, and short term secondments of 2-5 months involving experienced researchers, Superintendent Pharmacists and Designated Pharmacy Researchers will take their expertise gained in their own organisation and transfer this knowledge and skills base to that of the host organisation, while working fulltime on designated work packages. On completion of the research, seconded staff will return to their own organisation and transfer this new knowledge and skills set back into the originating organisation (in the form of training days, seminars, workshops and factsheets). Secondments with input from representatives of the Expert Advisory Panel will additionally optimise on knowledge transfer within a cultural and practical context, and the dissemination of work package outcomes at each phase back into originating organisations. Returning staff will be debriefed on return from secondments, and will recommend optimum processes and outcomes to disseminating and using the acquired knowledge both internally to inform current training and practice related activities.

**Broader training (e.g. communication, ethics, language training, and managerial skills)**

Continuing professional development will be provided to all participants at WIT, KCL and MRC during CODEMISUSED. All researchers will prepare and maintain a career development plan with support and guidance from their originating and host organisations. The Marie Curie Actions template will be used which outlines the relevant research work package, major accomplishments expected, short term objectives (anticipated publications, conference and seminar presentations, workshop attendance, training in new research, technical or communication skills, anticipated networking opportunities and community or professional activities) and long term career objectives (goals and further training required). Reviews of these plans will occur following each work package. Each partner academic institution will seek ethical approval for the project work, and will also deliver short training in health related research ethics for pharmacy designated researchers. For the requesting of information in South Africa, the translation of literature may necessitate support from an Afrikaans and Xhosa translator. Communication skills of all participants will be developed through the dissemination of results from the Dedicated CODEMISUSED project website, in peer-reviewed journals and by presentation at conferences at national and international levels.

# B.4 Implementation

## B.4.1. List of Work Packages

| Work package No | Work package title | Lead Beneficiary | Type of activity | Start-End month |
|---|---|---|---|---|
| WP1 | Project management and co-ordination | 1 | MGN | 1-48 |
| WP 2 | Systematic Review of Literature | 1 | TOK RTD | 2-6 |
| WP 3 | Web Survey of Medical Professionals | 1 | TOK RTD | 7-11 |

| | | | | |
|---|---|---|---|---|
| WP 4 | Web Survey of Pharmacy staff | 3 | TOK RTD | 12-16 |
| WP 5 | Web Survey of Addiction Treatment Providers | 2 | TOK RTD | 17-21 |
| WP 6 | Sweep Survey of Customers | 3 | TOK RTD | 20-25 |
| WP 7 | Internet Survey of Codeine Users | 2 | RTD | 5-26 |
| WP 8 | Interviews with Codeine Users, Misusers and Dependents. | 1 | TOK RTD | 14-25 |
| WP 9 | Innovation | 2 | TOK TR | 26-29 |
| WP 10 | Networking Support | ALL | TOK | 6-29 |
| WP 11 | Liaising, co-ordinating and linking to other European projects and programmes' | ALL | DISS | 17-29 |
| WP 12 | Sustainability | ALL | DISS | 28-30 |

## B.4.2. Work Packages description

| | | | |
|---|---|---|---|
| **Work package number** | **1** | **Planned start date:** 1st September 2013 | Month 1-48 |
| **Work package title** | Project management and co-ordination | | |
| **Beneficiary short name** | WIT | | |

**Objectives**
**O.1.1.**To start off the project at the ***'Start Up'*** meeting.
**O.1.2.**To effectively manage the project phases.
**O.1.3**To ensure communication between and within WPs.
**O.1.4** To ensure that the project proceeds according to plan;
**O.1.5** To ensure the quality of the project's deliverables through the development of quality assurance procedures.
**O.1.6** To ensure coordinated communication between all beneficiaries.
**O.1.7** To monitor the progress of work on the project and take corrective measures where appropriate.
**O.1.8** To manage the funding of the project;
**O.1.9** To report regularly as required to the European Commission; and organize and co-ordinate project reviews as required.

**Description of work**
**T.1.1.** Manage the secondment schedule and recruitment of researcher at KCL; and briefing of national pharmacy chains.
**T.1.2.** Network with national medical, pharmacy and treatment agencies.
**T.1.3.** Monitor the progress of work, dissemination and outreach on the project and take corrective measures where appropriate.
**T.1.4.** Manage the funding of the project; and organize and co-ordinate project reviews as required.
**T.1.5.** Deal with HR issues where appropriate.
**T.1.6** Implement a quality assurance mechanism throughout.

**Deliverables and Milestones**
**D.1.1.**Effective project management to completion.
**M.1.1.**Project Start-up and Management: Review of management, recruitment, secondment and work package scheduling.

**Seconded Fellows (Academic)**

| | |
|---|---|
| **MER 1** From **Partner** 1 to 6 | **Month** 4 to 5 and 14 and 26 |
| **MER 1** From **Partner** 1 to 4 | **Month** 6 to 13 and 15 to 24 |
| **Expertise:** Project coordinator | |
| **Tasks where involved:** T1.1-T1.6 (M.1.1) | |
| **MER 2** From **Partner** 1 to 6 | **Month** 20 to 21 |
| **MER 3** From **Partner** 2 to 6 | **Month** 7 to 8 |
| **MER 3** From **Partner** 2 to 4 | **Month** 18 to 19 |
| **MER 4** From **Partner** 2 to 6 | **Month** 20 to 21 |
| **MER 4** From **Partner** 2 to 4 | **Month** 23 to 24 |
| **MER 6** From **Partner** 3 to 6 | **Month** 14 to 15 |
| **MER 6** From **Partner** 3 to 5 | **Month** 19 to 20 |
| **MER 6** From **Partner** 3 to 4 | **Month** 23 to 24 |
| **MER 7** From **Partner** 3 to 6 | **Month** 7 to 8 |
| **MER 7** From **Partner** 3 to 4 | **Month** 11 to 12 |
| **MER 7** From **Partner** 3 to 5 | **Month** 25 to 26 |

**MER 8** From **Partner** 3 to 5 **Month** 5 to 8
**MER 8** From **Partner** 3 to 4 **Month** 13 to 14 and 26 to 27
**MER 8** From **Partner** 3 to 6 **Month** 16 to 24
**ER 9** From **Partner** 3 to 6 **Month** 7 to 10 and 15 to 19
**ER 9** From **Partner** 3 to 5 **Month** 13 to 14 and 21 to 22
**ER 9** From **Partner** 3 to 4 **Month** 25 to 28
**MER 10** From **Partner** 1 to 5 **Month** 2 to 22
**MER 11** From **Partner** 1 to 6 **Month** 6 to 7
**Expertises:** Project start up, management support, research and pharmacy practice expertise.
**Tasks where involved:** T1.1-T1.6 (M.1.1)

**Seconded Fellows (Pharmacy)**
**ESR 12** From **Partner** 4 to 2 **Month** 10 to 11
**ESR 12** From **Partner** 4 to 3 **Month** 22 to 23
**ESR 12** From **Partner** 4 to 1 **Month** 25 to 29
**ESR 13** From **Partner** 4 to 2 **Month** 13 to 14
**ESR 14** From **Partner** 4 to 2 **Month** 13 to 14 and 23
**ESR 15** From **Partner** 4 to 2 **Month** 21 to 22
**ESR 16** From **Partner** 4 to 2 **Month** 21 to 22
**ESR 17** From **Partner** 4 to 3 **Month** 17 to 18
**ESR 18** From **Partner** 4 to 3 **Month** 17 to 19
**ESR 19** From **Partner** 4 to 3 **Month** 19 to 20
**ESR 20** From **Partner** 4 to 3 **Month** 19 to 20
**ESR 21** From **Partner** 5 to 2 **Month** 5 to 6
**ESR 21** From **Partner** 5 to 1 **Month** 10 to 11
**ESR 21** From **Partner** 5 to 3 **Month** 17 to 18
**ESR 22** From **Partner** 5 to 2 **Month** 5 to 9 and 22 to 25
**ESR 22** From **Partner** 5 to 1 **Month** 12 to 14
**ESR 23** From **Partner** 5 to 3 **Month** 13 to 21
**ESR 24** From **Partner** 6 to 1 **Month** 16 to 17
**ESR 25** From **Partner** 6 to 2 **Month** 17 to 22
**ESR 25** From **Partner** 6 to 1 **Month** 22 to 26
**ESR 26** From **Partner** 6 to 2 **Month** 17 to 22
**ESR 26** From **Partner** 6 to 1 **Month** 22 to 26
**ESR 27** From **Partner** 6 to 3 **Month** 25 to 29
**Expertise:** Project management support and pharmacy superintendent.
**Tasks where involved:**T1.1-T1.6 (M.1.1)

**Recruited Fellows**
KCL Month 8 to 25
**ER 5** From **Partner** 2 to 6 **Month** 28 to29
**ER 5** From **Partner** 2 to 4 **Month** 26 to 27
**Expertise:** Research expertise and internet sourcing of material.
**Tasks where involved:**T1.1-T1.6 (M.1.1)

**Risk Analysis**
Marie Claire Van Hout was appointed to the work package to improve overall quality assurance and delivery. External sites will conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment.Quality Assurance will include: i) quality assurance specifications: For all deliverables quality assurance specifications (a document outline/product overview with table of contents and a brief explanation of the content intent for each section) will be prepared and distributed to all partners. Suggested amendments to the quality assurance specifications may then be incorporated into the final document; ii) oral reviews: Reviews of deliverables may be done at project meetings conducted by the project manager, where the reviewers state their comments and the authors produce a log of all comments; iii) Written reviews: For crucial deliverables, a more formal review process may be adopted, after an appropriate decision by the steering committee. This could entail the appointment of two or three reviewers who might produce a written report and iv) Acceptance of papers in peer-reviewed journals will also serve as an outside quality assurance mechanism

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|---|---|---|---|
| **Work package number** | **2** | **Planned start date: 1st October 2013** | Month 2-6 |
| **Work package title** | Systematic Review of Literature | | |
| **Beneficiary short name** | WIT | | |

**Objectives**
**O.2.1.**To conduct and report the findings of a scoping review to describe what is known about the legislative framework, production, distribution, and prevalence of use and misuse of codeine in the partner countries (Ireland, UK, South Africa), across the EU and internationally and to identify gaps in the evidence base.

**O.2.2.**To conduct and report the findings of a series of systematic reviews (including meta-analyses if appropriate) to establish the effectiveness of: interventions to prevent codeine misuse; and interventions to treat codeine misuse (including harm reduction strategies).

**Description of work**
**T.2.1.** An extensive database search to locate published literature required to meet Objectives 0.2.1.and 0.2.2. This search will be supplemented by:
T**T.2.2.**Governmental consultation for national data within the three partner countries.
**T 2.3.** Sourcing of documents and resources of international agencies such as EMA, EMCDDA, UNODC, WHO
T.2.4. An internet search for relevant papers from international conferences.
**T 2.5.** Requests to each respective Advisory Committee on Drugs and Data Coordination Unit, along with UNODC for ARQ information relating to Part III (Extent & patterns of drug use) and Part IV (Extent and patterns of and trends in drug crop cultivation and drug manufacture and trafficking – relating to products containing codeine).
**T 2.6.** Sourcing of INCB data on the amount of codeine based products manufactured in each country will be sought, in addition to data on the amount imported.
**T 2.7.** Hand searching and following up subject experts to identify grey literature
**T.2.7** Drafting and finalising outputs specified in *Deliverables and Milestones.*

**Deliverables and Milestones**
**D.2.1.** A full scoping review which draws on Arksey & O'Malley's (2005) framework to meet Objective 0.2.1.
**D.2.2**. Systematic reviews which synthesise research evidence on interventions to: prevent codeine misuse, reduce harm and treat codeine dependence to meet Objective 0.2.2.
**D.2.3**. Outputs to inform the practice of health professionals and policy makers in the partner countries and across the EU (e.g. product sales trend data reports, summaries of national data, fact sheets, papers for publication in academic and professional journals).

Reference: Arksey & O'Malley (2005) Scoping studies: towards a methodological framework. *Int.J. Social Research Methodology * (1): 19-32*

**Seconded Fellows (Academic)**

| | |
|---|---|
| **MER 1** From **Partner** 1 to 6 | **Month** 4 to 5 |
| **MER 1** From **Partner** 1 to 4 | **Month** 6 to 13 |
| **MER 8** From **Partner** 3 to 5 | **Month** 5 to 8 |
| **MER 10** From **Partner** 1 to 5 | **Month** 2 to 22 |
| **MER 11** From **Partner** 1 to 6 | **Month** 6 to 7 |

**Expertise:** Literature sourcing, write up of product sales trend data, meta-analysis and systematic review, country and integrated reports, and journal publications.
**Tasks where involved**:T2.1 – T2.7 (M2.1)

**Seconded Fellows (Pharmacy)**

| | |
|---|---|
| **ESR 21** From **Partner** 5 to 2 | **Month** 5 to 6 |
| **ESR 22** From **Partner** 5 to 2 | **Month** 5 to 9, |

**Expertise:** Pharmacy based and national data sourcing, screening and review of data and write up of product sales trend data, country and integrated reports, and journal publications.
**Tasks where involved**: T2.1 – T2.7 (M2.1)

**Risk Analysis:** Ian Norman is appointed as deputy lead to improve overall quality assurance and delivery. External sites will conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment. Data sourcing, retrieval, selection, charting/ extraction, collating, summarising and reporting will be scheduled for submission to WP Lead Marie Claire Van Hout. National and international agencies will be sent reminders in the event of non-response.

| **Work package number** | **3** | **Planned start date: 1st March 2014** | Month 7-11 |
|---|---|---|---|
| **Work package title** | Web Survey of Medical Professionals | | |
| **Beneficiary short name** | WIT | | |

**Objectives**
**O.3.1.** To examine the perspectives of a nationally representative sample of medical professionals in each participating country using a web based survey..

**Description of work**
**T3.1** To design a survey investigating participant perspectives on levels of and public health impact of therapeutic and non-therapeutic prescribed, OTC and web sourced codeine use, misuse and dependence, drug displacement patterns between prescribed and OTC/web sourced codeine, pain management strategies, preventative and referral tactics for use via the pharmacist, online and in the community, perspectives on the development of specific treatment policies and referral pathways, and ideas around CPD content and networking between medics and pharmacies in each model country.
**T 3.2** To host the survey on Survey Monkey.

**T.3.3** To recruit participants via respective Medical and General Practitioner associations.
**T.3.4.** To analyse the data using descriptive and inferential statistical tests.
**T3.5**To draft and finalise outputs in the form of country specific and integrated reports, factsheets and journal publications.

**Deliverables and Milestones**
**D.3.1.**Report on Web Survey of Medical professionals, and outputs in the form of country specific and integrated reports, factsheets and journal publications with a detailed medical profiling of perspectives around prescribed, OTC and online sourced codeine, and the potential trajectories of use, misuse and dependence within same.
**M.3.1.** Web Survey of Medical Professionals: Detail on prescribing patters, reasons and patterns of purchasing, complications and potential problematic use.

**Seconded Fellows (Academic)**

| | |
|---|---|
| **MER 1** From **Partner** 1 to 4 | **Month** 6 to 13 |
| **MER 3** From **Partner** 2 to 6 | **Month** 7 to 8 |
| **MER 7** From **Partner** 3 to 6 | **Month** 7 to 8 |
| **MER 7** From **Partner** 3 to 4 | **Month** 11 to 12 |
| **MER 8** From **Partner** 3 to 5 | **Month** 5 to 8 |
| **ER 9** From **Partner** 3 to 6 | **Month** 7 to 10 |
| **MER 10** From **Partner** 1 to 5 | **Month** 2 to 22 |
| **MER 11** From **Partner** 1 to 6 | **Month** 6 to 7 |

**Expertise:** Research expertise in survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:**T3.1-T3.5 (M3.1)

**Seconded Fellows (Pharmacy)**

| | |
|---|---|
| **ESR 12** From **Partner** 4 to 2 | **Month** 10 to 11 |
| **ESR 21** From **Partner** 5 to 1 | **Month** 10 to 11 |
| **ESR 22** From **Partner** 5 to 2 | **Month** 5 to 9 |

**Expertise:** Pharmacy practice contributing to survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs..
**Tasks where involved:**: T3.1-T3.5 (M3.1)

**Recruited Fellows**
KCL Month 8 to 25

| | |
|---|---|
| **ER 5** From **Partner** 2 to 6 | **Month** 28 to29 |
| **ER 5** From **Partner** 2 to 4 | **Month** 26 to 27 |

**Expertise:** Research expertise in survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:**T3.1-T3.5 (M3.1)

**Risk Analysis** Tara Carney was appointed to the work package to improve overall quality assurance and delivery. External sites will conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment. Design of survey will involve considerable debate prior to finalisation, input from all partners is crucial. Piloting of the survey on a small cohort of medical professionals operating in WIT and not partaking in the project will assist in final approval by the WP Lead Michelle Foley. Recruitment efforts will be optimised by existing country links with medical organisations.

| | | | |
|---|---|---|---|
| **Work package number** | **4** | **Planned start date: 1st August 2014** | Month 12-16 |
| **Work package title** | Web Survey of Pharmacy staff | | |
| **Beneficiary short name** | MRC | | |

**Objectives**
**O.4.1**. To examine and analyse the perspectives of a nationally representative sample of pharmacists, dispensing technicians and frontline staff in each model country using a web based survey.

**Description of work**
**T4.1** To design a survey investigating pharmacists' (from a representative sample of retail outlets in each country) perspectives in each country on levels and public health impact of prescribed, OTC and web purchased codeine use, misuse and dependence, alongside their perspectives on pharmacy based point of sale brief interventions, customer monitoring, referral pathways, addiction treatment guidelines for codeine, gaps in health service provision, potential health campaigns, and continuing networking between medics and pharmacists to address potential displacement toward customer dependency on codeine.
This includes one *focus group* in each country with a small sample of pharmacists (n=6-8). Pharmacy secondees can assist with these focus groups (e.g. taking notes) while seconded fellows will facilitate them.
**T 4.2** To host the survey on Survey Monkey.
**T.4.3** To recruit pharmacists from a representative sample of retail outlets in each country

by gaining access to a registration of national pharmacy councils via professional pharmacy associations.
**T.4.4.** To analyse the data using descriptive and inferential statistical tests**.**
**T4.5** To draft and finalise outputs in the form of country specific and integrated reports, factsheets and journal publications.
Please note: Seconded pharmacists will be taught how to use a quantitative software packaged e.g. SPSS in order to assist with the data analysis in month 16. Data analysis may begin in month 15 if the sample size is reached earlier. Tara Carney will head up preparation of country specific reports and factsheets, assisted by John Wells. Seconded academic fellows to assist preparation of journal article, as well as collaboratively agree on a suitable journal for submission.

**Deliverables and Milestones**
**D.4.1.** Report on Web Survey of Pharmacy staff and outputs in the form of country and comparative reports, factsheets and peer reviewed journal publications with a particular focus on the perspectives on health impact, areas of problematic use and are they able to discern problematic use/ users and then issues to relating to policy and legislative weaknesses and effectiveness, current regulation on the sale of codeine based products in each country, current customer monitoring and tracking systems, and experiences in dispensing prescribed and OTC codeine.
**M.4.1.** Web Survey of Pharmacy staff: Detail and list of most popular products for consumer's endorsement, perspectives on misuse trajectories.

**Seconded Fellows (Academic)**

| | |
|---|---|
| **MER 1** From **Partner** 1 to 4 | **Month** 6 to 13 and 15 to 24 |
| **MER 1** From **Partner** 1 to 6 | **Month 1**4 |
| **MER 6** From **Partner** 3 to 6 | **Month** 14 to 15 |
| **MER 7** From **Partner** 3 to 4 | **Month** 11 to 12 |
| **MER 8** From **Partner** 3 to 4 | **Month** 13 to 14 |
| **MER 8** From **Partner** 3 to 6 | **Month** 16 to 24 |
| **ER 9** From **Partner** 3 to 5 | **Month** 13 to 14 |
| **ER 9** From **Partner** 3 to 6 | **Month** 15 to 19 |
| **MER 10** From **Partner** 1 to 5 | **Month** 2 to 22 |

**Expertise:** Research expertise in survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T4.1-T4.5 (M4.1)

**Seconded Fellows (Pharmacy)**

| | |
|---|---|
| **ESR 13** From **Partner** 4 to 2 | **Month** 13 to 14 |
| **ESR 14** From **Partner** 4 to 2 | **Month** 13 to 14 |
| **ESR 22** From **Partner** 5 to 1 | **Month** 12 to 14 |
| **ESR 23** From **Partner** 5 to 3 | **Month** 13 to 21 |
| **ESR 24** From **Partner** 6 to 1 | **Month** 16 to 17 |

**Expertise:** Pharmacy practice contributing to survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T4.1-T4.5 (M4.1)

**Recruited Fellows**
KCL Month 8 to 25

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|---|---|
| **ER 5** From **Partner** 2 to 6 | **Month** 28 to29 |
| **ER 5** From **Partner** 2 to 4 | **Month** 26 to 27 |

**Expertise:** Research expertise in survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T4.1-T4.5 (M4.1)

**Risk Analysis** John Wells was appointed to the work package to improve overall quality assurance and delivery. External sites will conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment. Design of survey will involve considerable debate prior to finalisation, input from all partners is crucial. Piloting of the survey on a small cohort not partaking in the project will assist in final approval by the WP Lead Tara Carney. Recruitment efforts will be optimised by the national chains (Cara, Weldricks, Leading) and their existing country links with professional pharmacy organisations.

| **Work package number** | **5** | **Planned start date: 1st January 2015** | Month 17-21 |
|---|---|---|---|
| **Work package title** | Web Survey of Addiction Treatment Providers | | |
| **Beneficiary short name** | KCL | | |

**Objectives**
**O.5.1.**To examine the perspectives of a nationally representative sample of addiction treatment providers in each model country and will be analysed using a web based survey.

**Description of work**
**T5.1** To design a survey investigating participant perspectives on levels of codeine dependence, as primary, secondary and

tertiary drug of dependence, perspectives on appropriate treatment for this opiate drug as distinguished from the traditional substitution therapy, confounding factors such as pain management impacting on treatment outcome, and potential in/out patient psycho-social interventions.
**T 5.2** To host the survey on Survey Monkey.
**T.5.3** To recruit residential and outpatient addiction treatment providers in each country via the REITOX National Focal Point listing of addiction services (EMCDDA capacity building office) and South African Community Epidemiology Network on Drug Use (SACENDU) listing.
**T.5.4.** To analyse the data using descriptive and inferential statistical tests.
**T5.5** To draft and finalise outputs in the form of country specific and integrated reports, factsheets and journal publications.

**Deliverables and Milestones**
**D.5.1.** Report on Web Survey of Addiction Treatment Providers and outputs in the form of country and combined reports, factsheets and journal publications with perspectives on treatment provider's perspectives for improved referrals and treatment pathways for codeine abuse, involvement of pharmacy staff, medics, GPs and pain management experts.
**M.5.1.** Web Survey of Addiction Treatment Providers: An agenda for effective targeting and improved quality of treatment services for codeine dependent users.

**Seconded Fellows (Academic)**

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| **MER 1** From **Partner** 1 to 4 | **Month** 15 to 24 |
| **MER 2** From **Partner** 1 to 6 | **Month** 20 to 21 |
| **MER 3** From **Partner** 2 to 4 | **Month** 18 to 19 |
| **MER 4** From **Partner** 2 to 6 | **Month** 20 to 21 |
| **MER 6** From **Partner** 3 to 5 | **Month** 19 to 20 |
| **MER 8** From **Partner** 3 to 6 | **Month** 16 to 24 |
| **ER 9** From **Partner** 3 to 6 | **Month** 15 to 19 |
| **ER 9** From **Partner** 3 to 5 | **Month** 21 to 22 |
| **MER 10** From **Partner** 1 to 5 | **Month** 2 to 22 |

**Expertise:** Research expertise in survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T5.1-T5.5 (M 5.1)

**Seconded Fellows (Pharmacy)**

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|---|---|
| **ESR 15** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 16** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 17** From **Partner** 4 to 3 | **Month** 17 to 18 |
| **ESR 18** From **Partner** 4 to 3 | **Month** 17 to 19 |
| **ESR 19** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 20** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 21** From **Partner** 5 to 3 | **Month** 17 to 18 |
| **ESR 23** From **Partner** 5 to 3 | **Month** 13 to 21 |
| **ESR 24** From **Partner** 6 to 1 | **Month** 16 to 17 |
| **ESR 25** From **Partner** 6 to 2 | **Month** 17 to 22 |
| **ESR 26** From **Partner** 6 to 2 | **Month** 17 to 22 |

**Expertise:** Pharmacy practice contributing to survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T5.1-T5.5 (M5.1)

**Recruited Fellows**
KCL Month 8 to 25

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|---|---|
| **ER 5** From **Partner** 2 to 6 | **Month** 28 to29 |
| **ER 5** From **Partner** 2 to 4 | **Month** 26 to 27 |

**Expertise:** Research expertise in survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T5.1-T5.5 (M5.1)

**Risk Analysis** External sites will conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment. Design of survey will involve considerable debate prior to finalisation, input from all partners is crucial. Piloting of the survey on a small cohort of individuals involved in treatment and detoxification provision and not partaking in the project will assist in final approval by the WP Lead Paolo Deluca. Recruitment efforts will be optimised by existing country links with addiction treatment providers. A deputy lead, Charles Parry, has been appointed to the work package to improve overall quality assurance and delivery.

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|---|---|---|---|
| **Work package number** | **6** | **Planned start date: 1st May 2015** | Month 20-25 |
| **Work package title** | Sweep Survey of Customers | | |
| **Beneficiary short name** | MRC | | |

**Objectives**

**O.6.1.**To conduct sweep surveying of customers purchasing codeine based products on consecutive weeks, at varying times of the day in a stratified random sample of participating pharmacies in each model country.

Note: national coverage will be achieved by additional facilitation in national chains, Lloyds Ireland, and Dischem, South Africa.

**Description of work**

**T6.1** To design a survey investigating participant perspectives on customer attitudes towards the therapeutic and non-therapeutic use of prescribed and OTC codeine products, with analysis of self-reported prescribed, OTC and web sourced codeine purchasing, reasons for use of codeine based products, self-reported patterns of purchasing and use, codeine use outcomes over time, any poly medicine use, side effects of use and problematic use(based on Orriols L, Gaillard J, Lapeyre-Mestre M, & Roussin A (2009). Evaluation of abuse and dependence on drugs used for self-medication: a pharmacoepidemiological pilot study based on community pharmacies in France. *Drug Safety*. *32*:859-73)

**T 6.2** To sweep survey customers purchasing codeine based products on consecutive weeks, at varying times of the day in a stratified random sample of participating pharmacies in each model country.

**T.6.3** To analyse the data using descriptive and inferential statistical tests as stratified in relation to age, gender, ethnicity, education and income.

Please note: Seconded pharmacists will be taught how to use a quantitative software packaged e.g. SPSS in order to assist with the data analysis in month 16. Data analysis may begin in month 15 if the sample size is reached earlier. Tara to head up country specific reports and factsheets, and seconded academic fellows to assist preparation of journal article.

**T 6.4** To compare results with the Internet based survey results in WP7.

**T6.5** To draft and finalise outputs in the form of country specific and integrated reports, factsheets and journal publications.

**Deliverables and Milestones**

**D.6.1.** Report on Sweep Survey of Customers and outputs in the form of country and integrated reports, factsheets and peer – reviewed journal publications to include detail on reasons and patterns of purchasing and use, experiences of codeine use over time, dependence trajectories, experiences of problematic use, awareness of abuse potential, incurred adverse health consequences, experiences accessing pharmacies, medical advice around safe use of codeine, and ideas around improved pharmacy based supports, referral and treatment in each country.

**M.6.1.** Sweep Survey of Customers: Detail for evaluation of the usefulness of current national regulation on the OTC, prescribed and web based sale of codeine based products.

**Seconded Fellows (Academic)**

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| **MER 1** From **Partner** 1 to 4 | **Month** 15 to 24. |
| **MER 2** From **Partner** 1 to 6 | **Month** 20 to 21 |
| **MER 4** From **Partner** 2 to 6 | **Month** 20 to 21 |
| **MER 4** From **Partner** 2 to 4 | **Month** 23 to 24 |
| **MER 6** From **Partner** 3 to 5 | **Month** 19 to 20 |
| **MER 6** From **Partner** 3 to 4 | **Month** 23 to 24 |
| **MER 7** From **Partner** 3 to 5 | **Month** 25 to 26 |
| **MER 8** From **Partner** 3 to 6 | **Month** 16 to 24 |
| **ER 9** From **Partner** 3 to 5 | **Month** 21 to 22 |
| **ER 9** From **Partner** 3 to 4 | **Month** 25 to 28 |
| **MER 10** From **Partner** 1 to 5 | **Month** 2 to 22 |

**Expertise:** Research expertise in survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.

**Tasks where involved:** T6.1-T6.5 (M 6.1)

**Seconded Fellows (Pharmacy)**

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| **ESR 12** From **Partner** 4 to 1 | **Month** 25 to 29 |
| **ESR 12** From **Partner** 4 to 3 | **Month** 22 to 23 |
| **ESR 14** From **Partner** 4 to 2 | **Month** 23 |
| **ESR 15** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 16** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 19** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 20** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 22** From **Partner** 5 to 2 | **Month** 22 to 25 |
| **ESR 23** From **Partner** 6 to 3 | **Month** 13 to 21 |
| **ESR 25** From **Partner** 6 to 2 | **Month** 17 to 22 |
| **ESR 25** From **Partner** 6 to 1 | **Month** 22 to 26 |
| **ESR 26** From **Partner** 6 to 2 | **Month** 17 to 22 |
| **ESR 26** From **Partner** 6 to 1 | **Month** 22 to 26 |
| **ESR 27** From **Partner** 6 to 3 | **Month** 25 to 29 |

**Expertise:** Pharmacy practice contributing to survey design, final topics, targets and questions, recruitment of participants, data analysis and write up of outputs.

**Tasks where involved:** T6.1-T6.5 (M6.1)

**Recruited Fellows**
KCL Month 8 to 25
**ER 5** From **Partner** 2 to 6 **Month** 28 to29
**ER 5** From **Partner** 2 to 4 **Month** 26 to 27
**Expertise:** Research expertise in Internet monitoring, survey design, final topics, targets and questions for online discussions and survey, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T6.1-T6.5 (M6.1)

**Risk Analysis** Michael Bergin was appointed to the work package to improve overall quality assurance and delivery. External sites will conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment. Design of survey will involve considerable debate prior to finalisation, input from all partners is crucial. Piloting of the survey on a small cohort of customers not partaking in the project will assist in final approval by the WP Lead Tara Carney. Recruitment efforts will be optimised by existing customer relations in each site.

| **Work package number** | **7** | **Planned start date: 1st November 2013** | Month 5-26 |
|---|---|---|---|
| **Work package title** | Internet Survey of Codeine Users | | |
| **Beneficiary short name** | KCL | | |

**Objectives**
**O.7.1.**To conduct an internet monitoring exercise to identify trends in use of codeine-containing products by analysing a variety of online resources and surveying (online) individuals.

**Description of work**
**T.7.1.**To track users' endorsement and to estimate relative popularity of codeine based products (incl. patterns of use, preferred route of administration, dose, and combination with other products/substances)
**T.7.2.**To review and build a profile of effects (short and long term effects), side effects, risks of misuse/dependence of reported recreational use for each product; explore/assess the relative diffusion of codeine-containing products in *"non-registered*" online pharmacies and other online shops.
**T 7.3** To monitor two popular drug-related forums throughout the lifetime of the study for specific threads and posts on codeine-containing products.
**T 7.4** To analyse the data using descriptive analyses such as frequency and recency of posts and threads, content analysis for endorsement coding, as well as popularity ratio scores and probability estimates.
**T 7.5** To draft and finalise outputs in the form of factsheets and journal publications.

**Deliverables and Milestones**
**D.7.1.** Report on Internet Survey of Codeine Users and outputs in the form of factsheets and journal publications providing a list of most popular products both for consumers/users endorsement and online availability, and detailed profiles (effects, side effects etc) of each product.
**M.7.1.** Internet Survey of Codeine Users: Detail for evaluation of the usefulness of current regulation on the sale of codeine based products, and identify potential scope for improvement in the safe sale online.

**Seconded Fellows (Academic)**
**MER 1** From **Partner** 1 to 6 **Month** 4 to 5 and 14 and 26
**MER 1** From **Partner** 1 to 4 **Month** 6 to 13 and 15 to 24
**MER 2** From **Partner** 1 to 6 **Month** 20 to 21
**MER 3** From **Partner** 2 to 6 **Month** 7 to 8
**MER 3** From **Partner** 2 to 4 **Month** 18 to 19
**MER 4** From **Partner** 2 to 6 **Month** 20 to 21
**MER 4** From **Partner** 2 to 4 **Month** 23 to 24
**MER 6** From **Partner** 3 to 6 **Month** 14 to 15
**MER 6** From **Partner** 3 to 5 **Month** 19 to 20
**MER 6** From **Partner** 3 to 4 **Month** 23 to 24
**MER 7** From **Partner** 3 to 6 **Month** 7 to 8
**MER 7** From **Partner** 3 to 4 **Month** 11 to 12
**MER 7** From **Partner** 3 to 5 **Month** 25 to 26
**MER 8** From **Partner** 3 to 5 **Month** 5 to 8
**MER 8** From **Partner** 3 to 4 **Month** 13 to 14 and 26 to 27
**MER 8** From **Partner** 3 to 6 **Month** 16 to 24
**ER 9** From **Partner** 3 to 6 **Month** 7 to 10 and 15 to 19
**ER 9** From **Partner** 3 to 5 **Month** 13 to 14 and 21 to 22
**ER 9** From **Partner** 3 to 4 **Month** 25 to 28
**MER 10** From **Partner** 1 to 5 **Month** 2 to 22
**MER 11** From **Partner** 1 to 6 **Month** 6 to 7
**Expertise:** Research expertise in Internet monitoring, survey design, final topics, targets and questions for online discussions and survey, recruitment of participants, data analysis and write up of outputs.

**Tasks where involved:** T7.1-T7.5 (M 7.1)

**Seconded Fellows (Pharmacy)**

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| **ESR 12** From **Partner** 4 to 2 | **Month** 10 to 11 |
| **ESR 12** From **Partner** 4 to 3 | **Month** 22 to 23 |
| **ESR 12** From **Partner** 4 to 1 | **Month** 25 to 29 |
| **ESR 13** From **Partner** 4 to 2 | **Month** 13 to 14 |
| **ESR 14** From **Partner** 4 to 2 | **Month** 13 to 14 and 23 |
| **ESR 15** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 16** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 17** From **Partner** 4 to 3 | **Month** 17 to 18 |
| **ESR 18** From **Partner** 4 to 3 | **Month** 17 to 19 |
| **ESR 19** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 20** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 21** From **Partner** 5 to 2 | **Month** 5 to 6 |
| **ESR 21** From **Partner** 5 to 1 | **Month** 10 to 11 |
| **ESR 21** From **Partner** 5 to 3 | **Month** 17 to 18 |
| **ESR 22** From **Partner** 5 to 2 | **Month** 5 to 9 and 22 to 25 |
| **ESR 22** From **Partner** 5 to 1 | **Month** 12 to 14 |
| **ESR 23** From **Partner** 5 to 3 | **Month** 13 to 21 |
| **ESR 24** From **Partner** 6 to 1 | **Month** 16 to 17 |
| **ESR 25** From **Partner** 6 to 1 | **Month** 22 to 26 |
| **ESR 25** From **Partner** 6 to 2 | **Month** 17 to 22 |
| **ESR 26** From **Partner** 6 to 1 | **Month** 22 to 26 |
| **ESR 26** From **Partner** 6 to 2 | **Month** 17 to 22 |
| **ESR 27** From **Partner** 6 to 3 | **Month** 25 to 29 |

**Expertise:** Practice knowledge around web retailing of drugs and online pharmacies, and write up of outputs.
**Tasks where involved:** T7.1-T7.5 (M 7.1)

**Recruited Fellows**

KCL Month 8 to 25

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| **ER 5** From **Partner** 2 to 6 | **Month** 28 to29 |
| **ER 5** From **Partner** 2 to 4 | **Month** 26 to 27 |

**Expertise:** Research expertise in Internet monitoring, survey design, final topics, targets and questions for online discussions and survey, recruitment of participants, data analysis and write up of outputs.
**Tasks where involved:** T7.1-T7.5 (M 7.1)

**Risk Analysis** Michelle Foley was appointed to the work package to improve overall quality assurance and delivery. External sites with conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment. The risks posed by breaches of Internet security for the Internet surveys and the Dedicated CODEMISUSED Project website have been thoroughly considered by CODEMISUSED. Measures will be taken to substantially reduce this risk by use of firewalls, 128-bit encrypted data and databases, and the regular backing up of data, particularly personal information of participants. This will be done in line with current data storage and management regulations. Piloting of the survey on a small cohort of individuals not partaking in the project will assist in final approval by the WP Lead Paolo Deluca.
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| **Work package number** | **8** | **Planned start date: 1ST October 2014** | Month 14-25 |
| **Work package title** | Interviews with Codeine Users, Misusers and Dependents. | | |
| **Beneficiary short name** | WIT | | |

**Objectives**
**O.8.1.**To conduct interviews with Codeine Users, problematic users and those in addiction treatment in each model country.

**Description of work**
**T 8.1** To develop a purposive sampling strategy to identify non-dependent and dependent codeine users.
**T.8.2.**To recruit sample via referral from Work Packages 4, 5, 6 and 7, guided by a theoretical sampling strategy *'*.
**T.8.3.**To capture illustrative qualitative data pertaining to choices and decision making to use codeine (prescribed or otherwise), experience of sporadic and continued codeine use, experience of access to and support from treatment services, reinforcers for use, perceptions of risk and abuse potential, harm reduction practices, use of other drugs or medicines, adverse health consequences, favoured route of administration, non-therapeutic use and extraction of codeine from combination products (i.e. splicing or cold water extraction), opinions around medical prescribing, pharmacy dispensing and web based retail, and perspectives on treatment referral, uptake and outcomes.
**T 8.4** To analyse the data using a cyclical data analysis approach using the Qualitative Data Analysis (QDA) computer programme – NVivo 9. The use of NVivo will allow the researcher to probe the data, identify patterns and query data in relation to how w ell supported are the identified themes in relation to the data. Running coding matrix queries will facilitate this process of robustness. The concurrent use of memo writing within NVivo will also guide on-going data analysis.

**T 8.5**To draft and finalise outputs in the form of country and integrated reports, factsheets and journal publications to disseminate the qualitative findings on of codeine use; pathways to misuse or dependence and how dependence is reinforced and maintained; options for improved targeting of pharmacy based campaigns and health interventions, and, finally, recoommendations for the design of opiate treatment services for codeine dependent users in each country.

**Deliverables and Milestones**
**D.8.1**. Report on Interviews with Codeine Users, Misusers and Dependents and outputs in the form of country and integrated reports, factsheets and journal publications which will provide an understanding of individual and collective experiences of codeine use; pathways to misuse or dependence; how dependence is reinforced and maintained; recommendations for improved targeting of pharmacy based campaigns and health interventions, and, finally, recommendations for the design of opiate treatment services for codeine dependent users in each country.
**M.8.1**. Interviews with Codeine Users, Misusers and Dependents: Detail on user experiences and outcomes relating to codeine use, misuse and dependence.

**Seconded Fellows (Academic)**

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| **MER 1** From **Partner** 1 to 6 | **Month** 14 |
| **MER 1** From **Partner** 1 to 4 | **Month** 15 to 24 |
| **MER 2** From **Partner** 1 to 6 | **Month** 20 to 21 |
| **MER 3** From **Partner** 2 to 4 | **Month** 18 to 19 |
| **MER 4** From **Partner** 2 to 6 | **Month** 20 to 21 |
| **MER 4** From **Partner** 2 to 4 | **Month** 23 to 24 |
| **MER 6** From **Partner** 3 to 6 | **Month** 14 to 15 |
| **MER 6** From **Partner** 3 to 5 | **Month** 19 to 20 |
| **MER 6** From **Partner** 3 to 4 | **Month** 23 to 24 |
| **MER 7** From **Partner** 3 to 5 | **Month** 25 to 26 |
| **MER 8** From **Partner** 3 to 4 | **Month** 13 to 14 |
| **MER 8** From **Partner** 3 to 6 | **Month** 16 to 24 |
| **ER 9** From **Partner** 3 to 6 | **Month** 15 to 19 |
| **ER 9** From **Partner** 3 to 5 | **Month** 13 to 14 and 21 to 22 |
| **ER 9** From **Partner** 3 to 4 | **Month** 25 to 28 |
| **MER 10** From **Partner** 1 to 5 | **Month** 2 to 22 |

**Expertise:** Research expertise in the design of qualitative interview guides, qualitative data analytic techniques and social theoretical designs, and write up of outputs.
**Tasks where involved:** T8.1-T8.6 (M 8.1)

**Seconded Fellows (Pharmacy)**

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| **ESR 12** From **Partner** 4 to 1 | **Month** 25 to 29 |
| **ESR 12** From **Partner** 4 to 3 | **Month** 22 to 23 |
| **ESR 13** From **Partner** 4 to 2 | **Month** 13 to 14 |
| **ESR 14** From **Partner** 4 to 2 | **Month** 13 to 14 and 23 |
| **ESR 15** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 16** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 17** From **Partner** 4 to 3 | **Month** 17 to 18 |
| **ESR 18** From **Partner** 4 to 3 | **Month** 17 to 19 |
| **ESR 19** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 20** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 21** From **Partner** 5 to 3 | **Month** 17 to 18 |
| **ESR 22** From **Partner** 5 to 1 | **Month** 12 to 14 |
| **ESR 22** From **Partner** 5 to 2 | **Month** 22 to 25 |
| **ESR 23** From **Partner** 5 to 3 | **Month** 13 to 21 |
| **ESR 24** From **Partner 6** to 1 | **Month** 16 to 17 |
| **ESR 25** From **Partner 6** to 2 | M**onth** 17 to 22 |
| **ESR 25** From **Partner 6** to 1 | **Month** 22 to 26 |
| **ESR 26** From **Partner 6** to 2 | **Month** 17 to 22 |
| **ESR 26** From **Partner 6** to 1 | **Month** 22 to 26 |
| **ESR 27** From **Partner 6** to 3 | **Month** 25 to 29 |

**Expertise:** Practice expertise contributing to the design of qualitative interview guides, appropriate social theoretical approaches and write up of outputs.
**Tasks where involved:** T8.1-T8.6 (M 8.1)

**Recruited Fellows**

KCL Month 8 to 25

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| **ER 5** From **Partner** 2 to 6 | **Month** 28 to29 |
| **ER 5** From **Partner** 2 to 4 | **Month** 26 to 27 |

**Expertise:** Research expertise in the design of qualitative interview guides, qualitative data analytic techniques and social theoretical designs, and write up of outputs.
**Tasks where involved:** T8.1-T8.6 (M 8.1)

**Risk Analysis** Michael Bergin was appointed to the work package to improve overall quality assurance and delivery. External sites with conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment. Recruitment of participants may be hampered by issues relating to access, suspicion and mistrust, as drug use and dependence in particular is a hidden topic. Access will be assisted by the use of gatekeepers in each setting. Recruitment is assisted by referrals from Work Packages 4, 5, 6 and 7, and via the online forums *'Codeine Free'* and *'Overcount'*. Snowball sampling will be utilised with a cap on 2 participants to prevent social network bias. Piloting of the interview guide on a small cohort of individuals with experience of codeine dependence and not partaking in the project will assist in final approval by the WP Lead Marie Claire Van Hout.

| **Work package number** | **9** | **Planned start date: 1st October 2015** | Month 26-29 |
|---|---|---|---|
| **Work package title** | Innovation | | |
| **Beneficiary short name** | KCL | | |

**Objectives**

O.9.1. To draw upon the data gathered in WPs 2-8 to develop a practice guideline for pharmacists for the prevention and treatment of codeine use disorders.
O.9.2. To develop tools to assist pharmacists to implement the guideline within their clinical practice.

**Description of work**

T.9.1. To recruit a representative from each of the research partners (WIT, KCL, MRC, Weldricks, Leading, and Cara and other experts, as appropriate, to a Guideline Development Group which will develop the clinical guideline for pharmacists specified in Objective 0.9.1.
T.9.2. To draft questions to be: addressed in the literature reviews (WP2); included within the surveys (WPs 3-7); and to be incorporated within the interview schedules developed for WP9. (See Annex 9.1).
T.9.3. To develop the Guideline for Community Pharmacists (specified in Objective O.9.1) which will cover the following:
A) The prevalence of codeine use disorders and its health, social and economic consequences.
B) Pathways to codeine use disorders (illustrated by client profiles) and formulation/s which explain the maintenance of codeine use disorders.
C) The problems experienced by people who suffer from a codeine use disorders and their experiences of access to treatment and services.
D) Methods of liaison, consultation and tracking between community pharmacies, and between community pharmacists and other professionals and agencies.
E) Brief and specialist interventions for preventing codeine use, with particular reference to the role of the community pharmacist
F) Screening for codeine misuse in pharmacy settings
G) Recommended treatment pathways for codeine use disorders with particular reference to the contribution of community pharmacists.
H) Brief and specialist interventions for treating codeine use, with particular reference to the role of the community pharmacist
I) Guidelines for brand packaging, safe prescribing, dispensing and point-of-sale interventions.
T.9.4. To draw upon the practice guideline to develop the following *implementation tools* for pharmacists:
J) An education and training plan for pharmacists + slide set or prevention of codeine misuse + slide set or prevention of codeine misuse
L) A lay summary of the Guideline (specified in O.9.1.) for pharmacy customers
K) Materials for use in community pharmacists including: safe prescribing mini-guides (including screening tools/referral treatment advice); factsheets for pharmacy customers; point of sale guidance checklists. signage and other in-store design features

**Deliverables and Milestones**

**D.9.1.** To develop a practice guideline for pharmacists for the prevention and treatment of codeine use disorders.
**D.9.2**. To develop tools to assist pharmacists to implement the guideline within their clinical practice.
**M.9.1.**Innovative materials to support the prevention, identification, screening and treatment of codeine use disorders across the EU, with particular reference to the role of community pharmacies.

**Seconded Fellows (Academic)**

**MER 1** From **Partner** 1 to 6 **Month** 26
**MER 7** From **Partner** 3 to 5 **Month** 25 to 26
**MER 8** From **Partner** 3 to 4 **Month** 26 to 27
**ER 9** From **Partner** 3 to 4 **Month** 25 to 28
**Expertise:** Research expertise in the design of innovative outputs for use in policy and pharmacy practice.
**Tasks where involved:** T9.1-T9.8 (M9.1)

**Seconded Fellows (Pharmacy)**

**ESR 12** From **Partner** 4 to 1 **Month** 25 to 29
**ESR 25** From **Partner** 6 to 1 **Month** 22 to 26
**ESR 26** From **Partner** 6 to 1 **Month** 22 to 26
**ESR 27** From **Partner** 6 to 3 **Month** 25 to 29
**Expertise:** Practice expertise in the design of innovative outputs for use in policy and pharmacy practice.
**Tasks where involved:** T9.1-T9.8 (M9.1)

**Recruited Fellows**

KCL Month 8 to 25
**ER 5** From **Partner** 2 to 6 **Month** 28 to29
**ER 5** From **Partner** 2 to 4 **Month** 26 to 27
**Expertise:** Research expertise in the design of innovative outputs for use in policy and pharmacy practice.
**Tasks where involved:** T9.1-T9.8 (M9.1)

**Risk Analysis** Gerhard Beukes was appointed as Deputy Lead to the work package to improve overall quality assurance and delivery. Ian Norman, the WP Lead, will chair the Guideline Development Group. All partners will contribute either via attendance or by request of submission of ideas.

| **Work package number** | **10** | **Planned start date: 1st February 2014** | Month 6-48 |
|---|---|---|---|
| **Work package title** | Networking Support | | |
| **Beneficiary short name** | All partners | | |

**Objectives**
**O.10.1.**To disseminate project findings as they come available.

**Description of work**
**T.10.1.** Recommendations identified in **Work Packages 1-9**will be summarised on completion of each respective work package, and as a whole, with dissemination via the Dedicated CODEMISUSED Project website as short technical reports and factsheets, via project workshops, seminars, national and international conferences at various stages, and via the publication of national report, combined reports and scientific papers
**T.10.2.** Findings as they relate to prevalence, medical, pharmacy, addiction treatment, health promotion and proprietary/pharmaceutical practices, and their respective policies will be launched both via the dedicated CODEMISUSED Project website, with links to associated projects and national Pharmaceutical and Drug Research organisations, and in each country in their respective drugs and health research website, for example Ireland, "http://www.drugsandalcohol.ie"; UK, "http://www.drugscope.org.uk"; and South Africa "http://www.sahealthinfo.org".
**T.10.3** Scientific papers and reports will be forwarded to the EMA Pharmacovigilance and Risk Management Sector, EMA-CHMP, EMA-HPWG, EGPRN and EMCDDA for dissemination via the REITOX Network of National Focal Points, the Pharmaco Vigilant Steering Group and for consideration in '*Special Issue'* monographs, and other relevant international organisations (INCB, UNODC, WHO).
**T.10.4** Findings will be sent to each countries' Proprietary or Pharmaceutical Associations so as to boost involvement with product manufacturers.
**T.10.5** Professor Parry (MRC) will disseminate through the Technical Advisory Group of the UNODC/WHO joint programme on drug dependence treatment and care of which he is a member, David Bayever (Expert Advisory Panel) will disseminate findings through the South African Central Drug Authority, Dr Kevin Blake (Expert Advisory Panel) will disseminate findings through the Pharmacovigilance and Risk Management Sector in the Patient Health Protection Unit at the EMA, Professor Michael Evans Brown will disseminate via the Supply reduction and new trends unit, EMCDDA and Dr Richard Cooper (Expert Advisory Panel) as representative of the Royal Pharmaceutical Society UK will undertake same through member conferences, working groups, workshops, user forums '*Overcount'* and '*Codeine Free'* and emailed circulars.
**T.10.6** The Dedicated Project website will operate as public health portal and will offer information around the safe use of codeine, misuse, dependence and treatment options for the general public.
**T.10.7** Outreach activities will include Marie Curie Ambassadors (both academics and pharmacy secondees) visiting educational institutions to deliver short public seminars and training for students, workshops, conference seminars, podcasts via the CODEMISUSED website, e-Newsletters and E-bulletins and national media coverage.

**Deliverables and Milestones**
**D.10.1.** Project website and dissemination activity.
**M.10.1.** Networking Support: Dedicated project website, Seminars, Workshops, Publications, Reports and Conferences.

**Seconded Fellows (Academic)**

**MER 1** From **Partner** 1 to 6 **Month** 14 and 26
**MER 1** From **Partner** 1 to 4 **Month** 6 to 13 and 15 to 24
**MER 2** From **Partner** 1 to 6 **Month** 20 to 21
**MER 3** From **Partner** 2 to 6 **Month** 7 to 8
**MER 3** From **Partner** 2 to 4 **Month** 18 to 19
**MER 4** From **Partner** 2 to 6 **Month** 20 to 21
**MER 4** From **Partner** 2 to 4 **Month** 23 to 24
**MER 6** From **Partner** 3 to 6 **Month** 14 to 15

**MER 6** From **Partner** 3 to 5 **Month** 19 to 20
**MER 6** From **Partner** 3 to 4 **Month** 23 to 24
**MER 7** From **Partner** 3 to 6 **Month** 7 to 8
**MER 7** From **Partner** 3 to 4 **Month** 11 to 12
**MER 7** From **Partner** 3 to 5 **Month** 25 to 26
**MER 8** From **Partner** 3 to 5 **Month** 5 to 8
**MER 8** From **Partner** 3 to 4 **Month** 13 to 14 and 26 to 27
**MER 8** From **Partner** 3 to 6 **Month** 16 to 24
**ER 9** From **Partner** 3 to 6 **Month** 7 to 10 and 15 to 19
**ER 9** From **Partner** 3 to 5 **Month** 13 to 14 and 21 to 22
**ER 9** From **Partner** 3 to 4 **Month** 25 to 28
**MER 10** From **Partner** 1 to 5 **Month** 2 to 22
**MER 11** From **Partner** 1 to 6 **Month** 6 to 7
**Expertise: Expertise:** Research expertise in the dissemination of findings.
**Tasks where involved:** T10.1-T10.7 (M10.1)

**Seconded Fellows (Pharmacy)**
**ESR 12** From **Partner** 4 to 2 **Month** 10 to 11
**ESR 12** From **Partner** 4 to 3 **Month** 22 to23
**ESR 12** From **Partner** 4 to 1 **Month** 25 to 29
**ESR 13** From **Partner** 4 to 2 **Month** 13 to 14
**ESR 14** From **Partner** 4 to 2 **Month** 13 to 14 and 23
**ESR 15** From **Partner** 4 to 2 **Month** 21 to 22
**ESR 16** From **Partner** 4 to 2 **Month** 21 to 22
**ESR 17** From **Partner** 4 to 3 **Month** 17 to 18
**ESR 18** From **Partner** 4 to 3 **Month** 17 to 19
**ESR 19** From **Partner** 4 to 3 **Month** 19 to 20
**ESR 20** From **Partner** 4 to 3 **Month** 19 to 20
**ESR 21** From **Partner** 5 to 2 **Month** 5 to 6
**ESR 21** From **Partner** 5 to 1 **Month** 10 to 11
**ESR 21** From **Partner** 5 to 3 **Month** 17 to 18
**ESR 22** From **Partner** 5 to 2 **Month** 5 to 9 and 22 to 25
**ESR 22** From **Partner** 5 to 1 **Month** 12 to 14
**ESR 23** From **Partner** 5 to 3 **Month** 13 to 21
**ESR 24** From **Partner 6** to 1 **Month** 16 to 17
**ESR 25** From **Partner 6** to 2 **Month** 17 to 22
**ESR 25** From **Partner 6** to 1 **Month** 22 to 26
**ESR 26** From **Partner 6** to 2 **Month** 17 to 22
**ESR 26** From **Partner 6** to 1 **Month** 22 to 26
**ESR 27** From **Partner 6** to 3 **Month** 25 to 29

**Recruited Fellows**
KCL Month 8 to 25
**ER 5** From **Partner** 2 to 6 **Month** 28 to29
**ER 5** From **Partner** 2 to 4 **Month** 26 to 27
**Expertise:** Research expertise in the dissemination of findings.
**Tasks where involved:** T10.1-T10.7 (M10.1)

**Risk Analysis** Partners will ensure balanced dissemination via regional, national, EU and international avenues.

| **Work package number** | **11** | **Planned start date: 1st January 2015** | Month 17-29 |
|---|---|---|---|
| **Work package title** | Liaising, co-ordinating and linking to other European projects and programmes | | |
| **Beneficiary short name** | All Partners | | |

**Objectives**
**O.11.1.**To liaise, co-ordinate and link to other European projects and programmes through partner, Expert Advisory Panel and Post CODEMISUSED Panel networking, partnering and consultation with a wider network of medical, addiction and pharmacist experts..

**Description of work**
**T.11.1.**Partner, Expert Advisory Panel and Expert Post CODEMISUSED organisation and attendance of meetings, workshops, seminars and conferences for industry, government, academic, medical, pharmacy and addiction treatment stakeholders in each country throughout the duration of the project and as each work package is completed.
**T.11.2.**Collaborative meetings both in person and via Skype between academic, pharmacy and Expert Advisory Panel participants will provide a forum for discussion into the design and implementation of each phase given work package

research objectives, dissemination of research findings at each phase, targeting research outputs in the form of peer-reviewed publications, conference attendances, targeted brief interventions at point of sale and design of medical, pharmacist, health promotion and treatment CDP training, future strategic direction of the collaboration and new funding opportunities.
**T.11.3.**Knowledge and culture shared with external partners on publication in professional journals and policy documents issued by professional bodies.
**T.11.4.**Workshops, short seminars and visits to students at under and post graduate levels on their addiction, health and pharmaceutical programmes.
**T.11.5** Seconded and recruited researcher(s) will visit educational settings, primary care settings and community drugs projects to present key findings and raise awareness of the projects outputs.

**Deliverables and Milestones**
**D.11.1.** Final conference
**M.11.1.** Liaising, co-ordinating and linking to other European programmes: EGPRN, EMA-PRAC, EMA-CHMP, EMCDDA, INTO, INCB, WHO,SACENDU and national Pharmaceutical Societies.

**Seconded Fellows (Academic)**

| | |
|---|---|
| **MER 1** From **Partner** 1 to 6 | **Month** 26 |
| **MER 1** From **Partner** 1 to 4 | **Month** 15 to 24 |
| **MER 2** From **Partner** 1 to 6 | **Month** 20 to 21 |
| **MER 3** From **Partner** 2 to 4 | **Month** 18 to 19 |
| **MER 4** From **Partner** 2 to 6 | **Month** 20 to 21 |
| **MER 4** From **Partner** 2 to 4 | **Month** 23 to 24 |
| **MER 6** From **Partner** 3 to 5 | **Month** 19 to 20 |
| **MER 6** From **Partner** 3 to 4 | **Month** 23 to 24 |
| **MER 7** From **Partner** 3 to 5 | **Month** 25 to 26 |
| **MER 8** From **Partner** 3 to 4 | **Month** 26 to 27 |
| **MER 8** From **Partner** 3 to 6 | **Month** 16 to 24 |
| **ER 9** From **Partner** 3 to 6 | **Month** 15 to 19 |
| **ER 9** From **Partner** 3 to 5 | **Month** 21 to 22 |
| **ER 9** From **Partner** 3 to 4 | **Month** 25 to 28 |
| **MER 10** From **Partner** 1 to 5 | **Month** 2 to 22 |

**Expertise:** Research expertise in liaising, co-ordinating and linking to other European programmes.
**Tasks where involved:** T11.1-T11.5 (M11.1)

**Seconded Fellows (Pharmacy)**

| | |
|---|---|
| **ESR 12** From **Partner** 4 to 3 | **Month** 22 to 23 |
| **ESR 12** From **Partner** 4 to 1 | **Month** 25 to 29 |
| **ESR 14** From **Partner** 4 to 2 | **Month** 23 |
| **ESR 15** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 16** From **Partner** 4 to 2 | **Month** 21 to 22 |
| **ESR 17** From **Partner** 4 to 3 | **Month** 17 to 18 |
| **ESR 18** From **Partner** 4 to 3 | **Month** 17 to 19 |
| **ESR 19** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 20** From **Partner** 4 to 3 | **Month** 19 to 20 |
| **ESR 21** From **Partner** 5 to 3 | **Month** 17 to 18 |
| **ESR 22** From **Partner** 5 to 2 | **Month** 22 to 25 |
| **ESR 23** From **Partner** 5 to 3 | **Month** 13 to 21 |
| **ESR 24** From **Partner 6** to 1 | **Month** 16 to 17 |
| **ESR 25** From **Partner 6** to 1 | **Month** 22 to 26 |
| **ESR 25** From **Partner 6** to 2 | **Month** 17 to 22 |
| **ESR 26** From **Partner 6** to 1 | **Month** 22 to 26 |
| **ESR 26** From **Partner 6** to 2 | **Month** 17 to 22 |
| **ESR 27** From **Partner 6** to 3 | **Month** 25 to 29 |

**Recruited Fellows**
KCL Month 8 to 25

| | |
|---|---|
| **ER 5** From **Partner** 2 to 6 | **Month** 28 to29 |
| **ER 5** From **Partner** 2 to 4 | **Month** 26 to 27 |

**Expertise:** Research expertise in liaising, co-ordinating and linking to other European programmes.
**Tasks where involved:**T11.1-T11.5 (M11.1)

**Risk Analysis** Partners will ensure balanced and inclusive liasing, co-ordinating and linking to other European programmes.

| | | | |
|---|---|---|---|
| **Work package number** | **12** | **Planned start date: 1st December 2014** | Month 28-30 |
| **Work package title** | Sustainability | | |
| **Beneficiary short name** | All Partners | | |

**Objectives**
**O.12.1.** The long term outcome strategy is to develop an expert addiction, medical, health and pharmacy research cluster with high-quality outputs and strategic involvement with academic institutions and industry.
**O.12.2** CODEMISUSED will develop the critical mass necessary to attract future research funding which is intended to inform pharmaceutical manufacturers of codeine and other medicines of abuse.

**Description of work**
**T.2.1.** The **Expert Post CODEMISUSED** panel drawn from across the EU will interrogate the emerging findings from CODEMISUSED and evaluate their relevance and potential applicability in their country, advise on dissemination of outputs across different countries in the EU, and assist in the translation and validation of data collection instruments which would enable local surveys assessing codeine use, misuse and dependence in different EU countries.
**T.2.2.** As CODEMISUSED is a unique project on prescribed, OTC and web sold codeine use in an International, EU and national sense, new collaborations and partnerships will evolve as other countries undertake similar work to gain a sense of prescribed, OTC and web sold codeine use, misuse and dependence in their national regulatory context, and implement innovative outputs from CODEMISUSED in the form of brief point of sale interventions, customer monitoring and referral, signage and store designs and culturally specific professional training for professionals and pharmacy staff in the field of restricted and OTC medicines. Such collaboration efforts are likely to result in stronger links between partners and for enhanced opportunities for pharmacy partner and researcher collaboration. The dedicated CODEMISUSED Project website will enhance, support and foster new collaborations as the partners and Expert Advisory Panel discuss, present and disseminate the project's findings.

**Deliverables and Milestones**
**D.12.1.** Sustainability report.
**M.12.1.** Sustainability: Partner, Expert Advisory Panel and Expert Post CODEMISUSED Panel networking, partnering and consultation with a wider network of medical, addiction and pharmacist experts.

**Seconded Fellows (Academic)**
**ER 9** From **Partner** 3 to 4 **Month** 25 to 28
**Expertise:** Research expertise in building capacity and enhancement of future research direction post CODEMISUSED.
**Tasks where involved:** T12.1-T12.2 (M12.1)

**Seconded Fellows (Pharmacy)**
**ESR 12** From **Partner** 4 to 1 **Month** 25 to 29
**ESR 27** From **Partner 6** to 3 **Month** 28 to 29
**Expertise:** Practice expertise in employment of innovation piloting post CODEMISUSED.
**Tasks where involved:** T12.1-T12.2 (M12.1)

**Recruited Fellows**
KCL Month 8 to 25
**ER 5** From **Partner** 2 to 6 **Month** 28 to29
**ER 5** From **Partner** 2 to 4 **Month** 26 to 27
**Expertise:** Research expertise in building capacity and enhancement of future research direction post CODEMISUSED.
**Tasks where involved:** T12.1-T12.2 (M12.1)

**Risk Analysis** Partners will ensure continued work POST CODEMISUSED in the form of piloting of innovative outputs, and the use of findings for other RXED medication by increasing collaboration with other EU and international experts. All partners will feed in so as to ensure overall quality assurance and delivery.

## B.4.3. List of milestones and project deliverables

| Milestone no. | Milestone name | Lead beneficiary short name | Delivery date | Comments |
|---|---|---|---|---|
| M 1.1 | Project Start-up and Management | WIT | M3 | Review of management, recruitment, secondment and work package scheduling. |
| M 2.1 | Systematic Review of Literature | WIT | M7 | Detail on codeine sales, use, misuse and treatment trends in each model country. |
| M 3.1 | Web Survey of Medical Professionals | WIT | M12 | Detail on prescribing patters, reasons and patterns of purchasing, complications and potential problematic use. |
| M 4.1 | Web Survey of Pharmacy staff | MRC | M17 | Detail and list of most popular products for consumers endorsement, perspectives on misuse trajectories. |

| | | | | |
|---|---|---|---|---|
| M 5.1 | Web Survey of Addiction Treatment Providers | KCL | M22 | An agenda for effective targeting and improved quality of treatment services for codeine dependent users. |
| M 6.1 | Sweep Survey of Customers | MRC | M26 | Detail for evaluation of the usefulness of current national regulation on the OTC, prescribed and web based sale of codeine based products. |
| M 7.1 | Internet Survey of Codeine Users | KCL | M13 and M26 | Detail for evaluation of the usefulness of current regulation on the sale of codeine based products, and identify potential scope for improvement in the safe sale online |
| M 8.1 | Interviews with Codeine Users, Misusers and Dependents. | WIT | M26 | Detail on user experiences and outcomes relating to codeine use, misuse and dependence. |
| M 9.1 | Innovation | KCL | M30 | Detail to inform development of innovative outputs for use across the EU. |
| M 10.1 | Networking Support | All partners | M30 | Dedicated project website, Seminars, Workshops, Publications, Reports and Conferences. |
| M 11.1 | Liaising, co-ordinating and linking to other European programmes' | All partners | M30 | EGPRN, EMA-PRAC, EMA-CHMP, EMCDDA, INTO, INCB, WHO,SACENDU and national Pharmaceutical Societies. |
| M 12.1 | Sustainability | All partners | M30 | Partner, Expert Advisory Panel and Expert Post CODEMISUSED Panel networking, partnering and consultation with a wider network of medical, addiction and pharmacist experts. |

| **Del. no.** | **Deliverable Title** | **Nature** | **Dissemination level** | **Delivery date** |
|---|---|---|---|---|
| D.1.1 | Effective project management to completion. | R | CO | M31 |
| D2.1 | Report on Systematic Review of Literature and outputs in the form of product sales trend data, meta-analysis and systematic review, country and integrated reports, and journal publications. | R+ Pub | PU | M7 |
| D3.1 | Report on Web Survey of Medical professionals and outputs in the form of country specific and integrated reports, factsheets and journal publications. | R+ Pub | PU | M12 |
| D4.1 | Report on Web Survey of Pharmacy staff and outputs in the form of country and combined reports, factsheets and peer reviewed journal publications. | R+ Pub | PU | M17 |
| D5.1 | Report on Web Survey of Addiction Treatment Providers and outputs in the form of country and combined reports, factsheets and journal publications. | R+ Pub | PU | M22 |
| D6.1 | Report on Sweep Survey of Customers and outputs in the forum country and integrated reports, factsheets and peer –reviewed journal publications. | R+ Pub | PU | M26 |
| D7.1 | Report on Internet Survey of Codeine Users and outputs in the form of factsheets and journal publications. | R+ Pub | PU | M13 and 26 |
| D8.1 | Report on Interviews with Codeine Users, Misusers and Dependents and outputs in the form of country and integrated reports, factsheets and journal publications. | R+ Pub | PU | M26 |
| D9.1 | Innovation report and outputs in the form of a series of factsheets and user profiling for use in CPD modules for knowledge transfer between academics, and medical, health and pharmacist professionals; a series | R | PU | M30 |

| | | | | |
|---|---|---|---|---|
| | of recommendations for prescribing policies and brand packaging, medical monitoring of patient codeine use and networking with pharmacists; design of brief point of sale interventions in pharmacies (face to face and online), development of inter pharmacy tracking systems for customers misusing codeine; design of educational informational signage and other in store design issues, a series of specific recommendations and guidelines for codeine based treatment systems, country specific referral and treatment leaflets for problematic codeine use, and educational material on OTC and Rx'ed medicines of abuse for pharmacist continuing education. | | | |
| D10.1 | Project website and dissemination activity. | O | PU | M2 |
| D11.1 | Final conference | E | PU | M31 |
| D12.1 | Sustainability report | R | CO | M30 |

## B.4.4. Management structure, organisation and procedures

WIT will function as the primary point of contact for project partners throughout the duration of the project and allow clear communication of research strategies/methodology, action items/deliverables, and internal/external deadlines. The overall co-ordination of this project will be carried out by Dr Marie Claire Van Hout at WIT. Dr Marie Claire Van Hout will be responsible for communicating with the Commission and submitting all required technical and financial reports, the organisation of monthly Skype meetings, regular email updates, uploading of information onto the Dedicated CODEMISUSED Project website and partner networking and collaboration as the project progresses. The ability and commitment to large scale projects is demonstrated by the track record of all researchers, and their mutual histories in working together (KCL/WIT; WIT/MRC). Project support will be provided by the Research Support Units, IP Managers, financial and audit management support, Estates Office, IT and library facilities in all academic institutions. Internal Institutional structures within WIT supporting this research programme include the Office of the Secretary / Financial Controller WIT, the Dedicated Project Accountants in the Office of the Head of Research & Innovation which will provide on-going financial monitoring, planning and reporting to the governing board, all partners and the Higher Education Authority (HEA) in Ireland, and the Research Support Unit which provides institutional support for research communities and staff on project implementation relating to contract management, personnel recruitment and liaison with research funding bodies. HR recruitment and policies are in place in KCL, and a consortium agreement will guide partner recruitment strategies, conflict management and decision making protocols, gender balance and non-discrimination in the recruitment process, and demarcation of responsibilities in line with the EU rules for participation in FP7. At each pharmacy, HR matters are dealt with jointly by the Superintendent Pharmacist and policies documented in standard operating procedures.

The duration of CODEMISUSED is 48 months. A ***Start Up*** meeting was hosted by WIT and KCL in London, UK with CODEMISUSED completion conference hosted at WIT. One yearly project meeting will take place, which will review progress and offer training courses (research and complementary skills) to project teams. Meetings will take place regularly either in person in the form of short secondment trips and also monthly via Skype, so as to give all partners an overview of work package activities and preparations needed for the proceeding phases. All principal academic and pharmacy staff, along with the Expert Advisory Panel will attend. Bi annual meetings will additionally provide a partnership forum involving academic and pharmacy staff to discuss future directions of the group, and potential funding targets. Frequency and organisation of Management, Implementation and Monitoring Group (see **Figure 2**) meetings will provide a forum for decision-making, discussion of research progress and deliverables, work packages, research outputs, publication strategies, conference proceedings, design of innovations, future collaborative intentions and new funding opportunities (for example pharmaceutical involvement in tablet design and manufacture to deter codeine extraction by

users). The Dedicated CODEMISUSED Project website will act as portal for data storage, medium for transfer of findings and hosting of online team focus groups.

An active process will be created to manage the project to ensure communication between and within WPs; ensure that the project proceeds according to plan; ensure the quality of the project's deliverables through the development of quality assurance procedures; ensure coordinated communication between all beneficiaries; monitor the progress of work on the project and take corrective measures where appropriate; manage the funding of the project; report regularly as required to the European Commission; and organize and co-ordinate project reviews as required.All work package leads will be responsible for representing the project in the international arena and maintaining networks with external organisations, including EU/international agencies such EMCDDA, UNODC and national drug agencies. Additionally, a Deputy Lead will be appointed to the work package to improve overall quality assurance and delivery.

**Duties and responsibilities of the Work Package Leads (supported by Deputy Leads)**

• Day-to-day management of the project and planning of meetings.

•Supporting seconded and recruited staff in each country, and ensuring that work packages are carried out efficiently with outputs on time.

• Ensuring that all reports and work packages are written and presented on time.

• Consolidating the pharmacy and academic partnerships, and providing scientific leadership for the collaboration, along with consultation with the Expert Advisory Panel.

• Training of researchers and pharmacy staff in academic writing, methodologies, data analysis techniques and other generic skills where required.

• Co-ordinating all research outputs through seminars, workshops, peer-reviewed publications and conference presentations.

• Co-ordinating applications for further funding in the form of pharmaceutical company involvement in a second phase of investigation into tablet manufacture and harm reduction packaging. The use of low dosages of codeine (i.e. less than 30g) should be therapeutically evaluated as opposed to other analgesics with less unwanted side effects such as constipation, respiratory depression and more importantly, dependence, abuse and addiction.

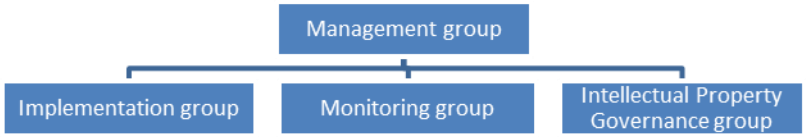
External sites with conduct a risk assessment, including induction to the site, awareness of hazards and fieldwork risk assessment.Quality Assurance will include: i) quality assurance specifications: For all deliverables quality assurance specifications (a document outline/product overview with table of contents and a brief explanation of the content intent for each section) will be prepared and distributed to all partners. Suggested amendments to the quality assurance specifications may then be incorporated into the final document; ii) oral reviews: Reviews of deliverables may be done at project meetings conducted by the project manager, where the reviewers state their comments and the authors produce a log of all comments; iii) Written reviews: For crucial deliverables, a more formal review process may be adopted, after an appropriate decision by the steering committee. This could entail the appointment of two or three reviewers who might produce a written report and iv) Acceptance of papers in peer-reviewed journals will also serve as an outside quality assurance mechanism.

### B.4.4.1. Network organization and management structure

A decision making structure will manage CODEMISUSED (see **Figure 2)** and will involve setting up a higher decision making group (**Management Group**) which will oversee issues such as research programmes, contingency planning, disagreements, research ethics, risk, resource allocation, intellectual property, teaching and learning strategies, and knowledge transfer, another working group more focused on the day to day implementation of work packages in partner countries (**Implementation Group**), a third more independent group **(Monitoring Group**) for monitoring secondments, progress and ensuring quality of work undertaken, and fourth group as **Intellectual Property(IP) Governance Group**. The Management Group will be the forum for decision making, co-operation and conflict resolution. All decisions will be based on negotiation and consensual decision making to resolve potential conflicts. The Parties shall use good faith efforts to resolve any dispute, claim or proceeding arising out of or relating to this Contract via the Management Group. If the matter is not resolved through negotiation, it shall be settled as agreed by the Management Group mediation in accordance with the Centre for

Dispute Resolution ("CEDR") Model Mediation Procedure (the "Model Procedure"). The mediation shall be before a single, jointly agreed upon, mediator.

**Figure 2Organisation and Management Structure**




**Management Group (Quarterly):** Van Hout, Beukes, Wells (R), McGuinness, Parry, Deluca, Fitzpatrick.
**Implementation Group (Monthly):** Wells (R), Carney, Foley, Du Plessis, Norman, Deluca, Van Hout, Fitzpatrick.
**Monitoring Group (Annual):** Cooper, Kissane, Evans Brown, Blakes, Bayeaver, Fitzpatrick, Wells (J), Van Hout, Parry, Deluca.
**IP Group (Annual):** Norman, Parry, Harris, Beukes, O Sullivan (Tech Officer, WIT).

### B.4.4.2. Financial management

Project support will be provided by the Research Support Units, IP Managers, financial and audit management support, Estates Office, IT and library facilities in all academic institutions.

### B.4.4.3. Recruitment strategy

The academic institutions have signed up to the European Charter for Researchers and abide by the Charter's general principles and requirements which specify the roles, responsibilities and entitlements of researchers as well as of employers and/or funders of research. In line with this Charter, all researchers are issued with a Contract of Employment for the duration of their contract, which details their working conditions, access to research training and continuous development, intellectual property rights and career development. WIT is a member of the HR Excellence in Research network.

All of the partners have an equal opportunities policy in place and no overt or covert discrimination based on race, sex, sexual orientation, religion or belief, disability or age will influence the selection process. Secondments will proceed according to Marie Curie regulations which will be signed by all parties in both originating and seconded organisations. The home organisation will continue to employ the participants during secondments and current employment contracts will remain in place. All secondees will receive the appropriate Marie Curie rates and expenses. Allowances for each researcher will be allocated to the originating organisation, with all associated research budget costs, overheads and management costs associated with that particular secondee allocated to the host organisation in order to facilitate the project. The recruited De Novo experienced researcher will be employed solely by the academic institution in question (KCL), and with the country specific social security scheme applicable. The seconded researchers and recruited researcher will be issued a contract from WIT/KCL/MRC and although they will spend some time working with the pharmacy partners, their salary will be paid from their academic institution. Similarly, pharmacy staff in the form of Superintendent Pharmacists and designated pharmacist *'researchers'* will be employed solely by their organisation and their salary will continue to be paid from there, irrespective of where they are placed. A portion of the research/transfer of knowledge programme expenses will be retained by the Coordinator to cover the cost of organising short visits for project meetings and conferences, with the remainder going to the host organisation for the period of time that that researcher is employed there. All associated management and overhead costs will be allocated to the originating organisations. Should expenses arise in a host organisation, that host organisation can apply to the originating organisation for expenses to be covered. The host organisations will also assist researchers in all administrative procedures required by the relevant authorities such as visas, work permits etc.

The De Novo researcher to be employed at KCL for 18 months will be recruited at the start of the project. Paper applications will be requested, shortlisted and interviewed by a panel consisting of Professor Norman, Dr De Luca, Dr Van Hout and Ms Tara Carney. The researcher will be offered the position based on their experience (ER 4-10 years) and individual expertise in the area of Internet drug use, as it relates to the projects objectives, and according a job specification agreed by all partners. As outlined, the researcher will be experienced in the areas of internet based drugs research, pharmacy

practice and codeine or opiate misuse and will be required to bring significant knowledge and expertise to the partnership. Job specifications will be defined in line with the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, and meet all the conditions for mobility as outlined in the Marie Curie Actions. CODEMISUSED will advertise in the following media sources:

1. WIT Website "http://www.wit.ie", KCL Website "http://www.kcl.ac.uk" and MRC website "http://www.mrc.ac.za".
2. EURAXESS Ireland "wwww.euraxess.ie" which feeds into Nature Jobs.
3. The UK based academic website "http://www.jobs.ac.uk" and Find a Postdoc website "http://www.findapostdoc.com", dedicated solely to postdoctoral job opportunities.
4. Existing strategic links within networks of addiction and pharmacy professionals at each organisation will also identify highly qualified postdoctoral staff willing to spend 12 months in the host organisation.

**B.4.4.4. Gender aspects**

CODEMISUSED will ensure non-discrimination in the recruitment process, by abiding to the Equality and Diversity Unit regulations at KCL with no more than 60% of the interview panel male or female. The researcher structure of CODEMISUSED has good gender balance and the project organisation structure at all four levels will ensure adequate gender balance with no more than 60% male/female.

**B.4.4.5. Intellectual property**

CODEMISUSED will adhere to principles outlined in the IP Management in Marie Curie Actions[1]. The CODEMISUSED partners have agreed that the optimum IPR Strategy for the project is that of the default position, namely that the pharmacy partners (Cara Pharmacy Group, Weldricks Ltd and the Leading Pharmacy Group) will retain the full ownership of all project results ("foreground"). The rational for this decision is primarily based on the fact that these entities are already successfully operating in the pharmacy practice markets and therefore are best positioned to have a significant socio-economic impact. In addition, access right in perpetuity will be provided to all foreground Intellectual Property to the research performing organisations (WIT, KCL, MRC) for the sole purpose of education and research. Access to background IP will be provided to each of the partners solely for the purpose of activities related to this project, and where necessary for commercialisation will be provided through bilateral negotiations on completion of the project. Each pharmacy partner will have exclusive rights to commercialise the Foreground in their respective geographies i.e. Cara Pharmacy Group in the Republic of Ireland and Northern Ireland, Weldricks in the United Kingdom and Leading Pharmacy Group in South Africa. Each pharmacy partner will have further rights to licence the Foreground IP outside of their respective geographies, while not licencing into geographies noted above of the other participating pharmacy partners. It is broadly agreed that each partner will bring any relevant background IP to the consortium, this will be detailed and finalised in the consortium agreement prior to the start of the project. WIT will establish an **IP Governance Group** with the primary purpose of:

- Identifying key intellectual property generated from the project.
- Managing the publication pipeline to ensure no unintended disclosures.
- Tracking, protecting and identifying routes for exploitation of intellectual property generated from the project.

The committee will be composed of one team member from each partner. WIT's in house Technical Transfer Officer (Research and Innovation Department) will partake in this group. The team will meet once per month to discuss on-going developments including the publication of results which may impact on commercialisation opportunities and hence be delayed. Specifically pharmacy parties have agreed that in the event of any arising invention, design or work, which they will apply for, obtain and/or maintain the relevant patent protection or any other Intellectual Property Right. The results from this project will be disseminated in numerous ways and consistent with the publication policy of not disclosing potentially commercially beneficial concepts. Outputs will be released as short technical reports and factsheets, via project workshops, seminars, national and international conferences at various stages, and via the publication of national reports, combined reports and scientific papers. All findings will be integrated and summarised with final recommendations formulated in national, EU and

[1] https://www.iprhelpdesk.eu/node/1298.

international reports. Findings as they relate to prevalence, medical, pharmacy, addiction treatment, health promotion and proprietary/pharmaceutical practices, and their respective policies will be launched both via the dedicated CODEMISUSED Project website, with links to the EMA's Pharmacovigilance Risk Assessment Committee (PRAC), national Pharmaceutical, Drug and Public Health Research organisations, and in each country in their respective drugs and health research websites. Subsequent scientific papers and reports will also be forwarded to the EMA-PRAC; EMA-CHMP, EMA-HPWG, EGPRN and EMCDDA for dissemination via the REITOX Network of National Focal Points, the Pharmaco Vigilant Steering Group and for consideration in '*Special Issue'* monographs, and other relevant international organisations (INCB, UNODC, WHO Technical Advisory Group of the UNODC/WHO joint programme on drug dependence treatment). The website will also operate as a public health portal and will offer information around the safe use of codeine, misuse, dependence and treatment options for the general public. Other outreach activities will include Marie Curie Ambassadors (both academics and pharmacy secondees) visiting educational institutions to deliver short public seminars and training for students, workshops, conference seminars, podcasts via the CODEMISUSED website, e-Newsletters and E-bulletins and national media coverage.

**According to the Special Clause 5 bis of Article 7 of the Grant Agreement, a mid-term review meeting will be organised during month 20-22 of the project. The venue and organisation of this meeting will be of the responsibility of the coordinator, Dr Van Hout and the timing and location of the meeting will be agreed with the REA project officer, Sandrine Jacobs.**

***B.4.4.6. Subcontracting (if applicable)***
N/A
***B.4.4.7. Third parties (other than subcontractors)(if applicable)***
*N/A*
***B.4.4.8. Small Equipment for SMEs (if applicable)***
*N/A*

# B.5 Impact

## B.5.1. Impact towards the policy objectives of the programme

CODEMISUSED will provide a unique and in depth investigation of prescribed, OTC and web based codeine use, misuse and dependence. Outputs will have great impact in each country and contribute to EU standards and guidelines for prescribing, dispensing, preventing customer harm, monitoring patterns of use, educating customers and in terms of potential applied health intervention, pharmacy, medical and health promotion practice, drug regulatory policies and management protocols for treating codeine dependence. The involvement of partners, each bringing to CODEMISUSED a unique set of skills, expertises and experiences of codeine use, misuse and dependence occurring in varied regulatory systems, creates a unique collaborative effort with distinct innovative outputs for use across the EU and in South Africa. It will create a unique portal for data on codeine use, misuse and dependence for use among scientists, pharmacists and health professionals, and has multiple target groups ranging from researchers, pharmacists, policy makers, drug users and the general public. The Expert Advisory Panel particularly via Professor Michael Evans Brown (EMCDDA) and Dr Kevin Blakes (EMA)increases the potential of impact of this proposed collaborative work, for the benefit of public health, pharmacy staff and drug workers and any other stakeholders (e.g. teachers, parents, care givers etc).As CODEMISUSED is a unique project on prescribed, OTC and web sold codeine use in an International, EU and national sense, new collaborations and partnerships will evolve as other countries undertake similar work to gain a sense of prescribed, OTC and web sold codeine use, misuse and dependence in their national regulatory context, and implement innovative outputs from CODEMISUSED in the form of brief point of sale interventions, customer monitoring and referral, signage and store designs and culturally specific professional training for professionals and pharmacy staff in the field of restricted and OTC medicines. Such collaboration efforts are likely to result in stronger links between partners and for enhanced opportunities for pharmacy partner and researcher collaboration. The dedicated CODEMISUSED Project website will enhance, support and foster new collaborations as the partners and Expert Advisory Panel discuss, present and disseminate the project's findings. The intended

national, international and WIT hosted conferences throughout and on completion of CODEMISUSED will further enhance the opportunity for continued and new collaboration between existing and new partners.

**CODEMISUSED's unique informative and innovative outputs**

1. A comparative profile of codeine product sales trends, and extent of codeine use, misuse and dependence in Ireland, the United Kingdom, and South Africa.
2. Country specific and integrated reports, factsheets and journal publications with detailed medical and treatment profiling of perspectives around prescribed, OTC and online sourced codeine, and the potential trajectories of use, misuse and dependence within same.
3. Country and combined reports, factsheets and journal publications with pharmacists' perspectives on the usefulness of current regulation on the sale of codeine based products in each country, current customer monitoring and tracking systems, and experiences in dispensing prescribed and OTC codeine.
4. A profiling of the variant trajectories of non-dependent and dependent codeine use to be found amongst the public, referring to purchasing habits and patterns of use via prescribed, OTC and web based retail sales in Ireland, the United Kingdom, and South Africa. The understanding of the lived experiences of codeine use, misuse or dependence, agendas for improved targeting of pharmacy based campaigns and health interventions, and design of opiate treatment services for codeine dependent users will be presented.
4. Country and combined reports, factsheets and journal publications with addiction treatment providers' perspectives have the potential to improve referrals and treatment pathways for codeine abuse with the involvement of pharmacy staff, GPs and pain management experts.
5. Innovative project outputs for use across the EU and South Africa. These unique model templates will inform customer or patient brief interventions (web and online), internal and inter pharmacy mechanisms for customer monitoring and tracking of codeine use over time, the role of community pharmacists in screening for codeine misuse and dependence, and doctor monitoring of patient codeine use and networking with pharmacists for use, providing support and information to those experiencing problematic use, the development of codeine specific referral and treatment modalities as distinct from traditional opiate based treatment systems, design of product packaging, educational signage and store designs, and development of useful CPD modules and training workshops for pharmacy, medical and addiction professionals across the EU and South Africa. As outlined the Expert Post CODEMISUSED panel will assist in optimising potential reach and utilisation of these deliverables.
6. Extensive knowledge transfer between the collaborating partners developing specialised expertise and know how, along with enhanced research portfolios.
7. Knowledge transfer garnered during CODEMISUSED by pharmacy staff which can be utilised in daily pharmacy practice to train staff, monitor customers seeking to purchase codeine based products, develop effective brief interventions delivered by pharmacists and frontline pharmacy staff, design appropriate referral mechanisms and codeine specific treatment modalities in each country.
8. There is potential for further collaboration with other experts in the field of addiction, medical and mental health through targeted dissemination of research findings with a view to developing a world class team of experts.
9. There is potential for leveraging of future research funding for pharmaceutical involvement and piloting of innovative outputs (customer monitoring systems, CPD training, brief point of sale interventions) through successful outcomes from this project (e.g. FP7 funding).
10. Commercial exploitation in the form of print media, signage and CPD training modules is envisaged through dissemination of information around user habits and codeine consumption pathways to national medical, pharmacy, pharmaceutical and other public health associations.

## B.5.2. Plans for exploitation of results and Dissemination strategy

CODEMISUSED provides clear and targeted dissemination strategies via a variety of mediums, by addressing and involving not only scientific audiences, but also students, early stage researchers, policy-makers, pharmacists, medical, health and drug professionals and the general public. A **Dissemination** strategy will be prepared by ***Month 2*** to guide and plan all the dissemination activities. CODEMISUSED will ensure that data generated in the project will be available to the broader research and public communities via the dedicated CODEMISUSED Project website, via dissemination in the EMA-PRAC, EGPRN, EMCDDA-REITOX Network, SACENDU South African MRC Network, Royal

Pharmaceutical Society UK, Royal College of Surgeons, Proprietary Association of Great Britain, RCGP Substance Misuse in Primary Care, Society of Study of Addiction, Irish Centre for Continuing Pharmaceutical Education, Irish Medicines Board etc and will take part in the European Commission's **Open Access Pilot in the Seventh Framework Programme (FP7).** CODEMISUSED's proposed scale of work has not yet been undertaken elsewhere in the world and offers a unique innovative partnership between academics and pharmacies, with innovative project model templates having the potential for use for other prescribed and OTC medicines. **Innovation Union Information and Intelligence system(I3S**) supports the creation of **'Knowledge Alliances'** between academia and pharmacy partners in CODEMISUSED to develop new curricula addressing innovation and skills gaps in the form of CPD training modules, pharmacy (web and face to face) brief interventions, inter pharmacy tracking systems for customers misusing codeine; educational informational signage and other in store design issues and guidelines for codeine based treatment systems. This material can be piloted using the **e-skills for innovation and competitiveness,** and **European Social Innovation pilot.** By ffacilitating mobility, supporting training and ensuring attractive careers CODEMISUSED's aims and objectives for academic and pharmacy partner transational mobility and optimal circulation and transfer of scientific knowledge ultimately seeks to address the issue of codeine use, misuse and dependence as public health issue and promote the safer use of codeine products in the general public **(Communication on the European Research Area).** CODEMISUSED's circulation of researchers gives them new experiences and new research skills, along with the promotion of mobility as a positive concept (**Youth on the Move)** CODEMISUSED supports this flagship's agenda relating to equipping people with the right skills for employment in terms of pharmacy staff up skilling in the area of codeine use, misuse and dependence, appropriate guidance and brief interventions, referrals and customer monitoring. It also has potential to create jobs in the piloting of aforementioned model templates (**An Agenda for New Skills and Jobs)**

The project will also endeavour to optimise on social media and new internet technologies to disseminate findings appropriately and in a timely fashion. The dedicated CODEMISUSED project website will be created to constitute the core element of the dissemination strategy. This will be designed at WIT, operative in ***Month 3*** and will be online so as to track and provide content in the form of web discussions and work package results as the project evolves. It will be linked to several well-known addiction, pharmaceutical practice and public health websites. This will facilitate access to project resources, outputs, newsletters, online events, podcasts and factsheets. The website will be developed in accordance with e-health recommendations from the EC and WHO. It will contain useful information for the general public with regard to the safe use of codeine, how to recognise problematic and dependent use, appropriate treatment pathways and relevant national service information. It will also be utilised by the research and pharmacy teams for restricted access to confidential data holdings soas to facilitate comparative analysis, and as platform for sharing and discussing early findings and their implications for policy, clinical practice and research within wider networks. Dissemination and utilisation of findings will occur in the partner pharmacy chains in the form of staff training seminars and workshops, submission of reports, development of in-house factsheets, specific training initiatives for frontline staff and in-house piloting of educational signage, customer brief interventions, tracking, and referral systems. Seconded and recruited researcher(s) will visit educational settings, primary care settings and community drugs projects to present key findings and raise awareness of the projects outputs. Public expert seminars, workshops for early stage researchers, students and interested parties and seminars held throughout CODEMISUSED will facilitate collaborative discussions from all partners, and dissemination of results and process outcomes as they occur. Members of the team with their existing international and EU network of colleagues, and ability to speak second languages (Xhosa, Afrikaans, Dutch, Italian) will assist in the dissemination, presentation, publication, and translation of outputs in terms of findings or innovation for use across the EU and South Africa. Academic and pharmacy partners will present findings at the closing CODEMISUSED conference hosted by WIT, and at national and international drugs, pharmaceutical, primary care, addiction and health related conferences. Academic and pharmacy partners will publish between one and five papers per work package, and submit to high impact international journals. The Marie Curie Actions will be acknowledged for its funding of the project where appropriate.

A dissemination network will be formed by bringing together not only the project partners but also all the relevant researchers in the area of codeine already identified through the drug and pharmaceutical networks, and existing contacts via the Expert Advisory Panel. This network will

contribute to the dissemination of the project findings in the appropriate scientific scenarios and as outreach activity within the public domain. These existing collaborations will then form an **Expert Post CODEMISUSED** panel for the dissemination of information and a series of standalone and integrated international, EU and national reports, short technical reports and factsheets to interested parties and the general public, and culturally appropriate CPD training modules for professionals across the EU and South Africa. These advisors drawn from across the EU will interrogate the emerging findings from CODEMISUSED and evaluate their relevance and potential applicability in their country, advise on dissemination of outputs across different countries in the EU, and assist in the translation and validation of local data collection instruments in different EU countries.

## B.5.3. Outreach activities

An **Outreach** strategy will be prepared by ***Month 2*** to guide and plan all the dissemination activities.

| Activity | Target audience |
|---|---|
| **Conferences and Symposia (National and International** | Experts, academics, researchers, medical professionals, pharmacists, pharmaceutical companies |
| **Project workshops and seminars** | Academics, researchers, medical professionals, pharmacists and pharmacy staff, early stage researcher, second and third level students, drug and community workers, at risk populations, general audience. |
| **Website** | All interested parties |
| **Social media (e-Bulletins, e-feeds, podcasts, twitter feeds, Facebook and U-tube, online forum)** | Academics, researchers, medical professionals, pharmacists and pharmacy staff, early stage researcher, second and third level students, drug and community workers, at risk populations, general audience. |
| **Scientific papers and reports** | Experts, academics, researchers, medical professionals, pharmacists, government and EU agencies |
| **Technical reports** | Experts, academics, researchers, medical professionals, pharmacists, government agencies and EU agencies |
| **Factsheets** | Public health agencies |
| **Public Forum** | General audience |
| **Innovation (pilot CPD Training modules, store signage and design recommendations, brief web and pharmacy intervention and customer tracking templates)** | Experts, academics, researchers, medical and health professionals, pharmacists and pharmacy staff. |

**As required by Annex II of the grant agreement, the coordinator will ensure that all publications and presentations by members of the project consortium - including all funded fellows - acknowledge the EU financial support received. This acknowledgement will specifically refer to the Marie Curie Industry-Academia Pathways and Partnerships (IAPP) action, as well as the project number** 611736 **and acronym** CODEMISUSED**.**

# B.6 Ethics

**The Beneficiaries accept to uphold the highest standards of scientific integrity and ethical conduct during the implementation of the grant agreement.**

Ethical issues involved in this project include consent, anonymity, data protection and protection from harm. Specific details around these issues and their management will be explored with WIT, KCL and MRC through Institutional Research Ethics Policies and Committees, with comprehensive guidelines for responsible practice in research. Professor Wells is an expert in research ethics and chairs the WIT Research Ethics Committee. He will advise the project. Copies of these ethical procedures (informed consent, anonymity, data protection) are available on request. The CODEMISUSED team recognises that individuals participating in brief and online surveys, and interviews might disclose activities necessitating actions, and will strive to minimise this by carrying out the research activities anonymously. The risk of disclosure requiring action in the user interviews will be minimised by interviewer and information leaflet/consent form clear explanation of rules of conduct on commencement. All user participants in the brief and online surveys and interviews will receive self-referral information (i.e. helpline contact details, and national services) in case of need to address their codeine use. The risks posed by breaches of Internet security for the Internet surveys and the Dedicated CODEMISUSED Project website have been thoroughly considered by CODEMISUSED. Measures will be taken to substantially reduce this risk by use of firewalls, 128-bit encrypted data and databases, and

the regular backing up of data, particularly personal information of participants. This will be done in line with current data storage and management regulations. All data collected from non-participants will be anonymised and no personally identifiable data will be stored. Analysis will be conducted using anonymised data.

| | Research on Human Embryo/ Foetus | YES | Page |
|---|---|---|---|
| | Does the proposed research involve human Embryos? | No | |
| | Does the proposed research involve human Foetal Tissues/ Cells? | No | |
| | Does the proposed research involve human Embryonic Stem Cells (hESCs)? | No | |
| | Does the proposed research on human Embryonic Stem Cells involve cells in culture? | No | |
| | Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos? | No | |
| | I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | Yes | |

| | Research on Humans | YES | Page |
|---|---|---|---|
| | Does the proposed research involve children? | No | |
| | Does the proposed research involve patients? | No | |
| | Does the proposed research involve persons not able to give consent? | No | |
| | Does the proposed research involve adult healthy volunteers? | Yes | 6-8 |
| | Does the proposed research involve Human genetic material? | No | |
| | Does the proposed research involve Human biological samples? | No | |
| | Does the proposed research involve Human data collection? | Yes | 6-8 |
| | I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | No | |

| | Privacy | YES | Page |
|---|---|---|---|
| | Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)? | Yes | 6-8 |
| | Does the proposed research involve tracking the location or observation of people? | Yes | 6-8 |
| | I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | No | |

| | Research on Animals | YES | Page |
|---|---|---|---|
| | Does the proposed research involve research on animals? | No | |
| | Are those animals transgenic small laboratory animals? | No | |
| | Are those animals transgenic farm animals? | No | |
| | Are those animals non-human primates? | No | |
| | Are those animals cloned farm animals? | No | |
| | I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | Yes | |

| | Research Involving non-EU Countries (ICPC Countries[2]) | YES | Page |
|---|---|---|---|
| | Is the proposed research (or parts of it) going to take place in one or more of the ICPC Countries? | Yes | 6-8 |
| | Is any material used in the research (e.g. personal data, animal and/or human tissue samples, genetic material, live animals, etc) :<br>a) Collected and processed in any of the ICPC countries? | Yes | 6-8 |
| | b) Exported to any other country (including ICPC and EU Member States)? | No | |
| | I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | No | |

[2] In accordance with Article 12(1) of the Rules for Participation in FP7, 'International Cooperation Partner Country (ICPC) means a third country which the Commission classifies as a low-income (L), lower-middle-income (LM) or upper-middle-income (UM) country. Countries Associated to FP7 do not qualify as ICPC Countries and therefore do not appear in this list.

| | Dual Use | YES | Page |
|---|---|---|---|
| | Research having direct military use | No | |
| | Research having the potential for terrorist abuse | No | |
| | I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL | Yes | |

**Recommendations as follows will be adhered to;**

1. Copies of Surveys will be provided.
2. Applicants will be provided with detailed information on privacy/confidentiality and the procedures that will be implemented for data collection, storage, access, sharing policies especially when third party countries are concerned, protection, retention and destruction. Confirmation that they comply with national and EU legislation will also be included.
3. The project will ensure that persons legally unable to consent will not participate in the project.
4. For the collaboration with institutions in South Africa, the ethical standards and guidelines compatible with those of FP7 will be rigorously applied. Measures for data protection (other than the internet connected ones) will be ensured.
5. When submitting application for scrutiny to the competent local/national relevant ethical boards/bodies/administrations for authorization/opinions/notifications detailed information will be provided on the procedures used for the recruitment of participants (e.g. number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants etc) and the nature of the material that will be collected (e.g. sensitive or personal data etc). It will be explicitly stated that children and adults unable to give informed consent will be excluded from participation.
6. When submitting the application for scrutiny to the competent local/national ethical boards/bodies for authorization/opinions/notifications, detailed information will be provided on the informed consent procedures that will be implemented. Copies of examples of Informed Consent Forms and Information Sheets will be included. These will be in language and terms understandable to the participants. Participants will have the right:

„h To know that participation is voluntary
„h To ask questions and receive understandable answers before making a decision
„h To know the degree of risk and burden involved in participation
„h To know who will benefit from participation
„h To know the procedures that will be implemented in the case of incidental findings
„h To know how their data will be collected, protected during the project and either destroyed or reused at the end of the research, if plan to reuse the data exist
„h Participants should be duly informed, and consented also for this further usage,
„h To withdraw themselves and their data from the project at any time.

7. When applying for ethical approval from the competent local /national Ethics Committees, detailed information will be provided on privacy/confidentiality and the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.
8. Prior to the commencement of the research and where applicable, copies of ethical approvals/opinions/notifications by the competent legal local/national Ethics Boards/Bodies/administrations will be submitted to the European Commission.
9. During the lifetime of this project the revised Directive 95/46/EC on Data Protection and Privacy will come into force, and the applicant will take this into account to ensure continuing compliance.
10. The applicant will provide detailed information to confirm that fair benefit sharing arrangements with stakeholders from non EU Country will be effectively managed during the project and that procedures will be implemented to facilitate effective capacity building.

## Update

Ethical approval received by WIT, Ireland, October 2013.
Ethical approval received by MRC, South Africa, October 2013

# PART C:

## Overall indicative project deliverables

**A3.2:**
**Deliverables**

| Project Number [1] | 611736 | Project Acronym [2] | CODEMISUSED |
|---|---|---|---|

One Form per Project

| | Recruitments | | | | | | Secondments | | | | | | | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Experienced researchers (<10) | | | Experienced researchers (>10) | | | Early stage researchers | | | Experienced researchers (<10) | | | Experienced researchers (>10) | | | |
| | Months | Researchers | % Fixed amount contract (1) | Months | Researchers | % Fixed amount contract (1) | Months | Researchers | % Fixed amount contract (1) | Months | Researchers | % Fixed amount contract (1) | Months | Researchers | % Fixed amount contract (1) | Months |
| WIT | 0 | 0 | 0% | 0 | 0 | 0% | 21 | 6 | 0% | 0 | 0 | 0% | 0 | 0 | 0% | 21 |
| KCL | 18 | 1 | 0% | 0 | 0 | 0% | 33 | 6 | 0% | 0 | 0 | 0% | 0 | 0 | 0% | 51 |
| SOUTH AFRICAN MEDICA | 0 | 0 | 0% | 0 | 0 | 0% | 27 | 6 | 0% | 0 | 0 | 0% | 0 | 0 | 0% | 27 |
| Unicare Pharmacy Ltd | 0 | 0 | 0% | 0 | 0 | 0% | 0 | 0 | 0% | 6 | 2 | 0% | 30 | 6 | 0% | 36 |
| H.I.Weldrick Ltd | 0 | 0 | 0% | 0 | 0 | 0% | 0 | 0 | 0% | 4 | 1 | 0% | 29 | 4 | 0% | 33 |
| Leading Pharmacy | 0 | 0 | 0% | 0 | 0 | 0% | 0 | 0 | 0% | 11 | 2 | 0% | 25 | 8 | 0% | 36 |
| Total | 18 | 1 | 0% | 0 | 0 | 0% | 81 | 18 | 0% | 21 | 5 | 0% | 84 | 18 | 0% | 204 |

# PART D:

## Overall maximum EU contribution

# A3.4:
## Total contribution per cost category

| Project Number [1] | 611736 | Project Acronym [2] | CODEMISUSED |
|---|---|---|---|

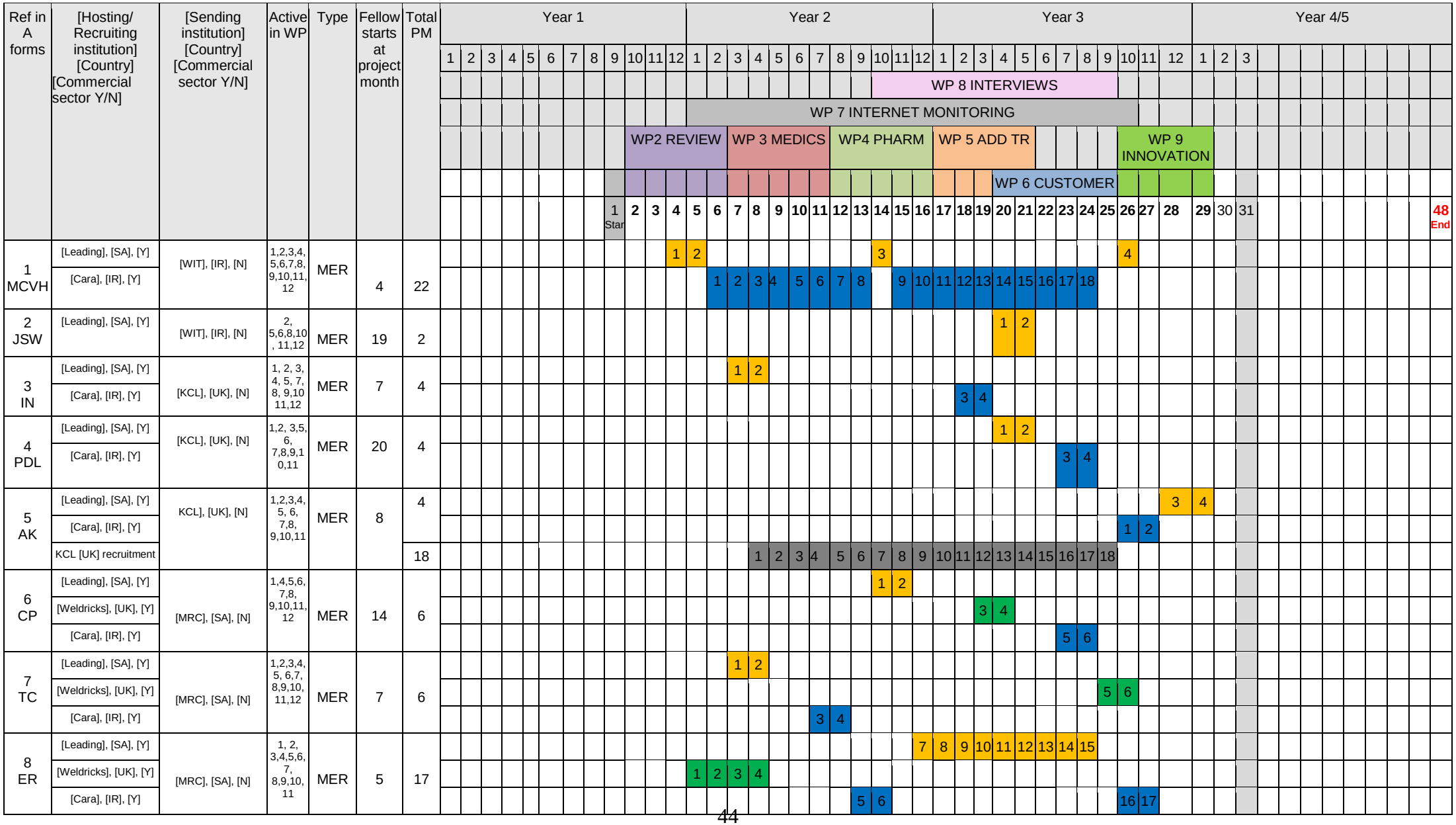
One Form per Project

| | Living allowance(1) | Mobility allowance(2) | Contribution to training expenses of eligible researchers and research/transfer of knowledge programme expenses (3) | Management activities (including audit certification) (4) | Contribution to overheads (5) | Other types of eligible expenses / specific conditions (6) | Total |
|---|---|---|---|---|---|---|---|
| Year 1 | 478,886.63 | 68,327.80 | 154,800.00 | 67,918.20 | 76,993.27 | 0.00 | 846,925.90 |
| Year 2 | 611,557.54 | 82,757.40 | 194,400.00 | 68,070.76 | 95,678.57 | 0.00 | 1,052,464.27 |
| Year 3 | 39,387.83 | 4,145.80 | 18,000.00 | 68,070.76 | 12,960.44 | 0.00 | 142,564.83 |
| Total | 1,129,832.00 | 155,231.00 | 367,200.00 | 204,059.72 | 185,632.28 | 0.00 | 2,041,955.00 |

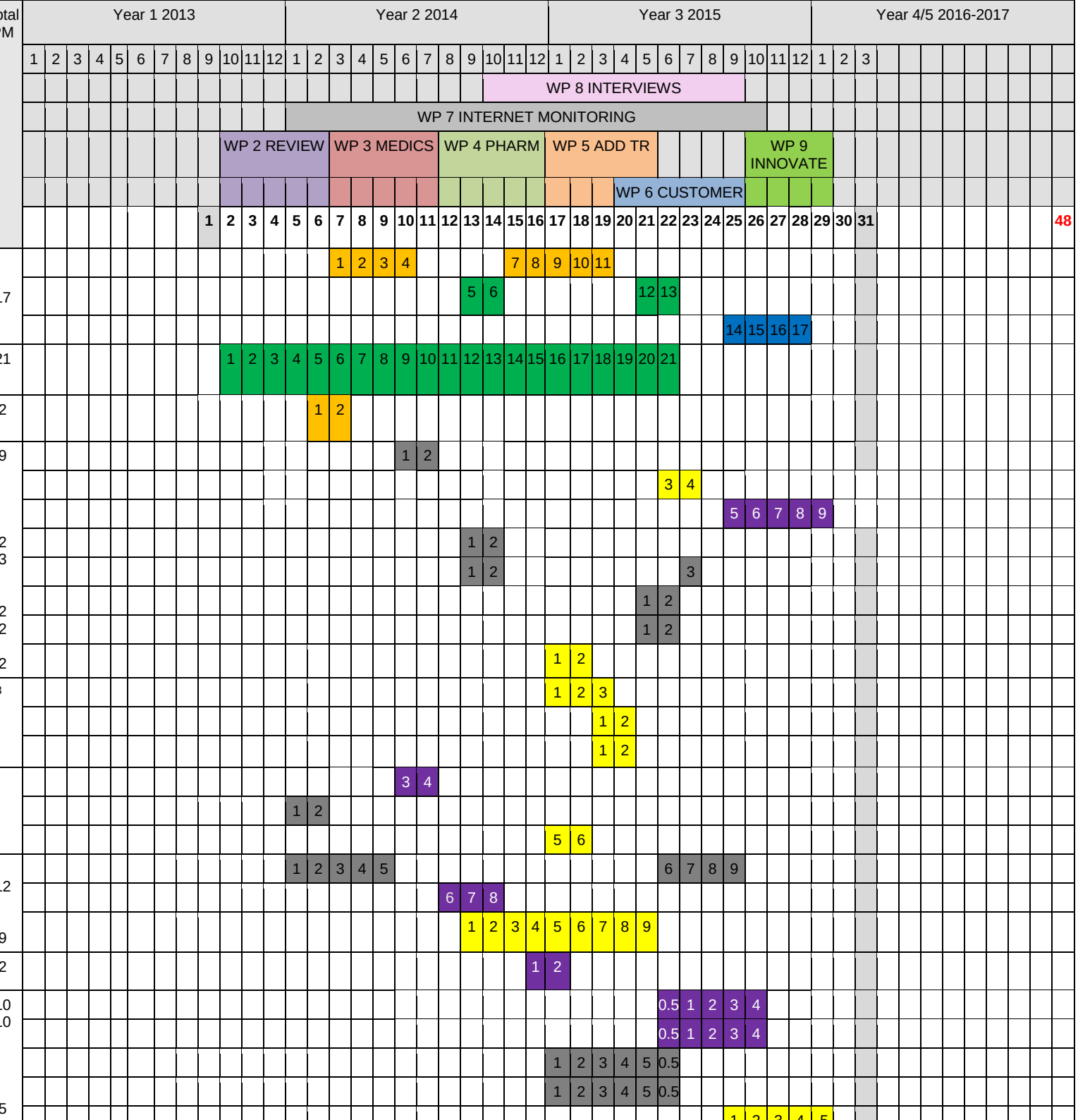
| | | | |
|---|---|---|---|
| WIT | | Cara | |
| KCL | | Weldricks | |
| MRC | | Leading | |

## Appendix 1 Gantt chart of recruitments and secondments

| Ref in A forms | [Hosting/ Recruiting institution] [Country] [Commercial sector Y/N] | [Sending institution] [Country] [Commercial sector Y/N] | Active in WP | Type | Fellow starts at project month | Total PM |
|---|---|---|---|---|---|---|
| 1 MCVH | [Leading], [SA], [Y] | [WIT], [IR], [N] | 1,2,3,4,5,6,7,8,9,10,11,12 | MER | 4 | 22 |
| | [Cara], [IR], [Y] | | | | | |
| 2 JSW | [Leading], [SA], [Y] | [WIT], [IR], [N] | 2, 5,6,8,10, 11,12 | MER | 19 | 2 |
| 3 IN | [Leading], [SA], [Y] | [KCL], [UK], [N] | 1, 2, 3, 4, 5, 7, 8, 9,10 11,12 | MER | 7 | 4 |
| | [Cara], [IR], [Y] | | | | | |
| 4 PDL | [Leading], [SA], [Y] | [KCL], [UK], [N] | 1,2, 3,5, 6, 7,8,9,10,11 | MER | 20 | 4 |
| | [Cara], [IR], [Y] | | | | | |
| 5 AK | [Leading], [SA], [Y] | KCL], [UK], [N] | 1,2,3,4, 5, 6, 7,8, 9,10,11 | MER | 8 | 4 |
| | [Cara], [IR], [Y] | | | | | |
| | KCL [UK] recruitment | | | | | 18 |
| 6 CP | [Leading], [SA], [Y] | [MRC], [SA], [N] | 1,4,5,6, 7,8, 9,10,11, 12 | MER | 14 | 6 |
| | [Weldricks], [UK], [Y] | | | | | |
| | [Cara], [IR], [Y] | | | | | |
| 7 TC | [Leading], [SA], [Y] | [MRC], [SA], [N] | 1,2,3,4, 5, 6,7, 8,9,10, 11,12 | MER | 7 | 6 |
| | [Weldricks], [UK], [Y] | | | | | |
| | [Cara], [IR], [Y] | | | | | |
| 8 ER | [Leading], [SA], [Y] | [MRC], [SA], [N] | 1, 2, 3,4,5,6, 7, 8,9,10, 11 | MER | 5 | 17 |
| | [Weldricks], [UK], [Y] | | | | | |
| | [Cara], [IR], [Y] | | | | | |



| Ref in A forms | [Hosting/ Recruiting institution] [Country] [Commercial sector Y/N] | [Sending institution] [Country] [Commercial sector Y/N] | Active in WP | Type | Fellow starts at project month | Total PM |
|---|---|---|---|---|---|---|
| 9 SD | [Leading], [SA], [Y] | [MRC], [SA], [N] | 2, 3, 4, 5, 6, 7, 8, 9,10, 11, 12 | ER | 7 | 17 |
| | [Weldricks], [UK], [Y] | | | | | |
| | [Cara], [IR], [Y] | | | | | |
| 10 MF | [Weldricks], [UK], [Y] | [WIT], [IR], [N] | 1,2,3,4,5,6,7,8,9,10,11,12 | MER | 2 | 21 |
| 11 MB | [Leading], [SA], [Y] | [WIT], [IR], [N] | 2,7 | MER | 6 | 2 |
| 12 PM | [KCL], [IR], [N] | [Cara], [IR], [Y] | 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 | ESR | 10 | 9 |
| | [MRC], [IR], [N] | | | | | |
| | [WIT], [IR], [N] | | | | | |
| 13 Cara | KCL], [UK], [N] | | | | 13 | 2 |
| 14 Cara | [KCL], [UK], [N] | | | | 13 | 3 |
| 15 Cara | KCL], [UK], [N] | | | | 21 | 2 |
| 16 Cara | [KCL], [UK], [N] | | | | 21 | 2 |
| 17 Cara | [MRC], [SA], [N] | | | | 17 | 2 |
| 18 Cara | MRC], [SA], [N] | | 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 | ESR | 17 | 3 |
| 19 Cara | MRC], [SA], [N] | | | | 19 | 2 |
| 20 Cara | MRC], [SA], [N] | | | | 19 | 2 |
| 21 RH | [WIT], [IR], [N] | [Weldricks], [UK], [Y] | 2, 3, 4, 5, 7, 8, 10, 11, 12 | ESR | 5 | 6 |
| | [KCL], [UK], [N] | | | | | |
| | [MRC], [SA], [N] | | | | | |
| 22 AR | [KCL, [UK], [N] | [Weldricks], [UK], [Y] | 2,3, 4, 5, 6, 7, 8, 10, 11 | ESR | 5 | 12 |
| | [WIT], [IR], [N] | | | | | |
| 23 TC | [MRC], [SA], [N] | | | | 13 | 9 |
| 24 GB | [WIT], [IR], [N ] | [Leading], [SA], [Y] | 2, 4, 5, 6, 7, 8, 9, 10, 11, 12 | ESR | 16 | 2 |
| 25 (CM) 26 (SS) | [WIT], [IR], [N] | Leading], [SA], [Y] | 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 | ESR | 17 | 10 |
| | [WIT], [IR], [N] | | | | 17 | 10 |
| 25 (CM) 26 (SS) | [KCL], [UK], [N] | | | | | |
| | [KCL], [UK], [N] | | | | | |
| 27 (SOS) | [MRC], [SA], [N] | | | | 25 | 5 |



| | Researcher months | % |
|---|---|---|
| **Total no. of secondments** | 186 | 91.18 |
| Inter-sectoral secondments | 186 | 100 |
| Intra-national secondments | 61 | 32.7 |
| **Total no. of recruitments** | 18 | 8.8 |
| **Total no. of secondments + recruitments** | 204 | 100 |

# Appendix 2: Extract from the 2013 PEOPLE Work Programme

## Structure of the cost categories applicable for IAPP (adapted from Table 3.1 and 3.3 of the WP)

This information does not substitute the relevant information of the 2012 People Work Programme, which should be consulted for further details.

| 1<br>Monthly living allowance | 2<br>Monthly mobility allowance | 3<br>Contribution to the training expenses of eligible researchers and research/transfer of knowledge programme expenses | 4<br>Management activities (including audit certification if applicable) | 5<br>Contribution to overheads | 5<br>Other types of eligible expenses / specific conditions |
|---|---|---|---|---|---|
| Flat rate of :<br><br>38 000 Euro/year for ESRs<br>58 500 Euro/year for ERs and<br>87 500 Euro/year for MERs<br><br>Rate for individual countries is obtained by applying the correction coefficients listed in Table 3.2 of the WP. | Flat rate allowance to cover expenses linked to the personal household, relocation and travel expenses of the researcher and her/his family in the host country: reference rate of EUR 700 for researchers without a family and EUR 1000 for researchers with a family.<br><br>Rate for individual countries is obtained by applying the correction coefficients listed in Table 3.2 of the WP. | Flat rate of EUR 1800 per researcher-month managed by the host organisations to contribute for expenses related to the participation of researchers to training activities; expenses related to research costs; execution of the training/partnership project and contribution to the expenses related to the co-ordination between participants. | Maximum of 10% of the total EU contribution. | 10% of direct costs except for subcontractors and the costs of the resources made available by third parties which are not used in the premises of the beneficiary. | **Applicable for participating SMEsonly**:<br>Small equipment expenses up to a maximum of 10% of the total contribution to the SME participant, if: duly justified for the project, on the basis of real costs and after prior agreement by the REA. |

## EU27 and Associated Countries correction coefficients (adapted from Table 3.2 of the WP)

For other countries (such as ICPC and third countries), please consult the WP.

| | |
|---|---|
| Austria | 106.2 |
| Belgium | 100.0 |
| Bulgaria | 62.7 |
| Cyprus | 83.7 |
| CzechRepublic | 84.2 |
| Denmark | 134.1 |
| Estonia | 75.6 |
| Finland | 119.4 |

| | |
|---|---|
| France | 116.1 |
| Germany | 94.8 |
| Greece | 94.8 |
| Hungary | 79.2 |
| Ireland | 109.1 |
| Italy | 106.6 |
| Latvia | 74.3 |
| Lithuania | 72.5 |

| | |
|---|---|
| Luxembourg | 100 |
| Malta | 82.2 |
| Netherlands | 104.1 |
| Poland | 77.1 |
| Portugal | 85.0 |
| Romania | 69.5 |
| Slovak Rep. | 80.0 |
| Slovenia | 89.6 |

| | |
|---|---|
| Spain | 97.7 |
| Sweden | 118.6 |
| UK | 134.4 |

| | |
|---|---|
| Albania | 63.1 |
| Bosnia & Herz. | 74.4 |
| Croatia | 83.0 |
| FYROM | 60.6 |
| Iceland | 95.0 |
| Israel | 96.4 |
| Liechtenstein | 109.9 |
| Moldova | 64.3 |

| | |
|---|---|
| Montenegro | 65.0 |
| Norway | 140.6 |
| Serbia | 74.0 |
| Switzerland | 119.6 |
| The Faroes | 134.1 |
| Turkey | 98.4 |

## APPENDIX

**DRAFT QUESTIONS TO BE INCORPORATED INTO THE OTHER WORK PACKAGES TO COLLECT DATA TO INFORM THE PRACTICE GUIDELINE SPECIFIED IN OBJECTIVE O.9.1.**

**WP 2 LITERATURE REVIEWS (Lead Marie-Claire)**

***Scoping Review to address:***

- The prevalence of codeine use disorders and its health, social and economic consequences.
- *What is the prevalence of codeine use disorders across the partner countries, the EU and internationally?*
- *What are the health, social and economic consequences of codeine use disorders?*

Pathways to codeine use disorders

- *What is known about how codeine use disorders begin, become established and are maintained?*
- Methods of liaison, consultation and tracking between community pharmacies, and between community pharmacists and other professionals and agencies.
- *What methods are used for tracking codeine misusers across services and agencies and how effective are they?*

*How do codeine misuse services liaise across agency and professional boundaries? And how effective are these liaison methods?*

Recommended treatment pathways for codeine use disorders with particular reference to the contribution of community pharmacists.

- *What treatment pathways are available for codeine use disorders and what is the evidence of their effect?*
- *What is the place and contribution of community pharmacists to treatment pathways?*

Guidelines for brand packaging, safe prescribing, dispensing and point-of-sale interventions.

- *What guidelines exist for brand packaging? Are they adopted and what's the evidence on their effects on sales and use of codeine?*
- *What do (should) doctors and other prescribers do before prescribing a codeine product?*
- *What do (should) pharmacists and other dispensers do before dispensing a codeine product?*
- *What do (should) prescribers do to titrate the codeine dose?*
- *What steps do (should) prescribers and dispensers take to ensure patient safety?*

Guidelines for codeine use disorders available internationally

- *What guidelines and implementation tools are available internationally for the identification and management of codeine use disorders?*

***Systematic Reviews to address:***

Brief and specialist interventions for preventing codeine use, with particular reference to the role of the community pharmacist

*What psychological/physical/social organizational interventions are available to prevent codeine misuse and how effective are they?*

*What is the contribution of the community pharmacist to these interventions?*

Screening for codeine misuse in pharmacy settings

- *What screening tools and procedures are available for identification of codeine misusers and how effective are they?*

**WPs 3, 4, 5, 6, 7 WEB SURVEYS**

***CORE QUESTIONS FOR THE SURVEYS***

A) Methods of liaison, consultation and tracking between community pharmacies, and between community pharmacists and other professionals and agencies.

*Sample Questions:*

*What methods are used for tracking codeine misusers across services and agencies and how effective are they?*

- *How do codeine misuse services liaise across agency and professional boundaries? And how effective are these liaison methods?*

B) Recommended treatment pathways for codeine use disorders with particular reference to the contribution of community pharmacists.

- *Sample Questions:*
- *What treatment pathways are available for codeine use disorders and what is the evidence on their effectiveness?*
- *What is the place within and contribution of community pharmacists to treatment pathways?*

C) Brief and specialist interventions for preventing codeine use, with particular reference to the role of the community pharmacist

- *Sample Questions:*
- *What interventions are available to prevent codeine misuse and how effective are they?*
- *What is the contribution of the community pharmacist to these interventions?*

D) Guidelines for brand packaging, safe prescribing, dispensing and point-of-sale interventions.

- *Sample Questions:*
- *What guidelines exist for brand packaging? Are they adopted and what's the evidence on their effects on sales and use of codeine?*
- *What do (should) doctors and other prescribers do before prescribing a codeine product?*
- *What do (should) pharmacists and other dispensers do before dispensing a codeine product?*
- *What do (should) prescribers do to titrate the codeine dose?*
- *What steps do (should) prescribers, and dispensers do to ensure patient safety?*

E) Screening for codeine misuse in pharmacy settings

- *Sample Questions:*
- *What screening tools and procedures are available for identification of codeine misusers and how accurate are they?*

F) Brief and specialist interventions for treating codeine use, with particular reference to the role of the community pharmacist

- *Sample Questions:*

*What interventions are available to treat codeine misusers and how effective are they?*

*What is the contribution of the community pharmacist to these interventions?*

## *ADDITIONAL QUESTIONS FOR THE DIFFERENT WORK PACKAGES*

### WP7 INTERNET SURVEY OF CODEINE USERS

*Sample Questions:*

What are the characteristics (profiles) of people who use codeine?

### WP8 INTERVIEWS WITH CODEINE USERS, MISUSERS AND DEPENDENTs

- Pathways to codeine use disorders
- *Sample Questions:*
- *What is known about how codeine use disorders begin, become established and are maintained?*

The problems experienced by people who suffer from a codeine use disorders and their experiences of access to treatment and services.
Guidelines for brand packaging, safe prescribing, dispensing and point-of-sale interventions.

- *Sample Questions:*
- *What effect does brand packaging have on customers' purchasing behavior and subsequent use of codeine.*

Brief and specialist interventions for treating codeine use, with particular reference to the role of the community pharmacist

- *Sample Questions: What interventions would you prefer/find acceptable?(Compare preferences across client profiles). ?*