SECURE

Secondary prEvention of CardiovascUlaR disease in the Elderly trial

Deliverable 2.2:

Detailed dissemination plan

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Description: Document describing all dissemination actions planned during the course of the project

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Glossary

Abbreviation/ acronym	Description
CV(D)	Cardiovascular (Disease)
ESC	European Society of Cardiology
EU	European Union
FACT	French Alliance for Cardiovascular Trials
FOCUS	Fixed-dose Combination Drug for Secondary Cardiovascular Prevention
GA	General Assembly
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IPR	Intellectual Property Right
NGO	Non-Governmental Organisation
SCReN	Spanish Clinical Research Network
WHF	World Heart Federation
WHO	World Health Organisation
WP	Work Package

1. Executive Summary

SECURE's Work Package 2 (WP2) covers the dissemination, communication and innovation management activities of the project. They are coordinated by ARTTIC with supervision from the Coordinator CNIC. All partners contribute to these work-package activities.

The dissemination objectives of the SECURE project and the approach to be used to target each of the above groups are clearly defined in section 2.

Dissemination actions will be followed up using a tool developed by the project office. A first overview of the planned events and their periodicity is presented in section 3, together with plans for the communication material.

For all partners, their role in dissemination and communication activities is presented with respect to their field of competence, as well as the corresponding resources they have allocated (see section 4).

2. Objectives and targets

2.1 Objectives

The aim of SECURE dissemination plan is two-fold:

1. To disseminate research and clinical knowledge about the effects of a polypill strategy on cardiovascular (CV) outcomes generated by the project and to assure that the progress made in SECURE is assimilated into the scientific community's state of the art and the end user patients.
2. To raise the awareness of the project to the general public, communicating on the European Union (EU) research & innovation programmes, its added value and benefit to address important societal problems, whilst creating and reinforcing synergies between SECURE and other EU initiatives.

2.2 Target groups

Target Group	Objective(s)	Means
Cardiology and Cardiovascular Professional Societies and Associations	(i) Promotion of the use of a polypill strategy to the existing usual care in reducing events (CV death, recurrence of acute myocardial infarction, stroke and revascularization) in secondary prevention in the elderly (ii) Adoption of the findings of SECURE and other key translational research into routine clinical practice	Presentation at key national and international congresses Dissemination of educational material via SECURE website SECURE position papers incorporating relevant findings
Users and healthcare stakeholders: - **Specialist Physicians** - **Scientific Societies** - **Nursing Associations** - **Health Care Authorities**	Increase awareness of SECURE scientific, clinical and educational activities in the field of secondary CV prevention in the elderly	National/international congresses & workshops Scientific publications Website Brochures Newsletters
Scientific community, related EU and US initiatives	Collaborate and exchange with linked groups and initiatives with similar objectives to avoid duplication of effort and maintain rapid progress in secondary CV prevention research and clinical practice	SECURE website International Congresses & Workshops – joint initiatives Scientific publications
Patients and Patient Associations	Improve awareness of Cardiovascular Disease (CVD) – at risk subjects, warning symptoms, pathophysiology, and available treatment options. Publicity concerning SECURE objectives and results	Public website Press releases Brochures Newsletters

Target Group	Objective(s)	Means
General public	Broad dissemination of educational material concerning CVD - awareness of CVD, risk factors and prevention, presenting symptoms, new research findings Promote public funding programmes supporting CVD research and its benefits for society	Public website Press releases Mass media articles (mainstream press, health magazines, flyers in primary care)
Policy makers, funding authorities	Maintain awareness of the SECURE programme – progress, results, innovation, economic benefits, impact of the project for improved healthcare	National/international conferences Scientific publications Press releases Open meetings with research funders and healthcare policy makers Public website

3. Dissemination and communication actions

3.1 Follow-up of actions

During the project, partners will generate foreground, i.e. new knowledge/results. Before disseminating own foreground related to SECURE outside the consortium, e.g. through a publication or a conference talk, a partner needs to ensure that no other partner objects to the publication of this foreground.

Before disseminating foreground, the partners should therefore respect the following rules, as per the CA:

- At least 45 days prior notice of any dissemination activity (including publications) shall be given to the other partners involved in the concerned work being disseminated, including information concerning the planned dissemination activity and data.
- Following notification, any of those partners may object within 30 days, if it considers that its legitimate interests in relation to its foreground or background could suffer disproportionately great harm. In such cases, the dissemination activity may not take place unless appropriate steps are taken to safeguard these legitimate interests.

For notification, the following procedure should be applied:

1) The partner wishing to disseminate foreground should first inform the Coordinator and the Project Office (secure-management@eurtd.com) about the planned dissemination.
2) The Project Office will assist the partner to prepare and send an e-mail to secure-partners@eurtd.com, which will include a summary of the intended dissemination.
3) If a partner has an objection to the dissemination, he/she should send an e-mail to the disseminating partner and add secure-management@eurtd.com in copy. The e-mail should contain a justification for the objection which clearly shows that the objecting partner's legitimate interest is harmed. The objection can include:
   - a request to cancel the dissemination
   - suggested modifications of the dissemination
4) Without an answer from any of the other partners before the deadline (30 days according to usual Consortium Agreement's clauses), the dissemination is considered validated and the dissemination can be done.

ARTTIC has set up a list on SECURE internal website (Dissemination Activities) that will be used to follow-up on requests and approvals and will then serve as reference to report these activities to the EC.

3.2 Publications

Over the five-year project duration the consortium will communicate results in high impact scientific journals and scientific meetings. SECURE research partners are leaders in their fields with publications in the highest impact journals on medicine such as:

- New England Journal of Medicine
- Journal of the American College of Cardiology
- Lancet
- Journal of the American Medical Association
- Circulation

- European Heart Journal
- Nature Reviews in Cardiovascular Medicine

The SECURE Publication plan will include at least:

- A draft paper about the project should be prepared by end 2015
- The final study results will be published in several peer-reviewed journals.

It is the duty of the WP leaders to look for opportunities for dissemination and to make opportunities for authorship. Criteria for publications will be based on the rules on authorship, such as the ones stipulated in the British Journal of Medicine: http://www.bmj.com/about-bmj/resources-authors/article-submission/authorship-contributorship) to acknowledge the level and nature of contribution of key individuals in publications arising from SECURE.

Authorship credit will be based only on substantial contribution to all the following criteria:

- Conception and design, or analysis and interpretation of data
- Drafting or critically revising the article for important intellectual content
- Final approval of the version to be published.

Each author should have participated sufficiently to take public responsibility for its content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.

The Project Office will have a role in the follow-up of the publication approval process by the General Assembly (GA) in distributing the publications and following up the approval process. The GA will be involved in screening the publication drafts and identifying protectable knowledge and contacting the authors to check if Intellectual Property Right (IPR) (e.g. patents) has been applied for already.

After completion of the study, a clinical study report will be prepared according to the ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use) Guideline for Structure and Content of Clinical Study Reports (ICH E3) by CNIC in collaboration with the SECURE consortium.

The results of the study will be published in a peer review journal.

All publications and presentations must be based upon the clinical study report.

All information supplied by the Sponsor in connection with this study will remain the sole property of the Sponsor and is to be considered confidential information. No confidential information will be disclosed to others without obtaining prior written consent from the Sponsor and will not be used except in the performance of this study.

If an Investigator wishes to publish results from this clinical study, written permission to publish must be obtained from the Sponsor in advance. As some of the information regarding the investigational product and development activities at the Sponsor may be of a strictly confidential nature, the Sponsor must first review any publication manuscript prior to their submission to journals, meetings or conferences.

The Sponsor will publish and present data from this study after all partners have been asked to comment and approve the publication.

3.3 Production of material

All institutions involved in SECURE have dedicated departments for divulgation in the public mass media of each participating country that will collaborate in the communication of the project results. To support these activities, SECURE will prepare the following set of tools.

3.3.1 Communication material

SECURE logo, templates, standard PowerPoint presentation, poster, leaflet, brochures and other communication documents will be based on a common graphic chart. SECURE dissemination and communication activities will have a consistent, attractive but sober image recognisable within the scientific community and wider public.

In August 2015 a flyer that can be distributed during events was produced. The first opportunity was the European Society of Cardiology (ESC) Congress that took place in London from 29 August to 2 September. Most consortium members have attended this event, and it was used as opportunity for the General Assembly to meet.

A leaflet presenting the aims of SECURE and expected impact and results will be produced within the first project year (by May 2016) and presented in Deliverable 2.3 “Project leaflet” (public).

A poster showing the project objectives, main activities and foreseen results is planned to be produced by May 2017 and presented in Deliverable 2.4 “SECURE Poster” (public).

3.3.2 Public website

A public website is available since August 2015: http://www.secure-h2020.eu. Its structure and current contents are detailed in a dedicated report available here. On the homepage you can find a layman’s presentation in slide-share format targeting the non-specialist audience. The website also includes details about the project objectives and work plan, together with the list of participants and key personnel involved.

Throughout the project it will become a major tool to present the project research outcomes to a wide audience with: educational material concerning secondary prevention for CVD in the elderly, regular updates of on-going activities within the SECURE programme, progress of research activities, latest results and publications, all highlighting the funding support from the European research programme and wide societal benefits. Educational material will be based on information already available on partner websites such as the ones of CNIC and Ferrer and also on reference organisation websites, notably the World Health Organisation (WHO) and the World Heart Federation (WHF).

3.3.3 Specialist and general press releases

Press releases will be issued at major milestone dates of the project (notably launch of the clinical trial and publication of the final results). Some will be targeting stakeholders of CVD related research and healthcare and some will be addressed to the general public and available on the SECURE website.

3.3.4 Brochures

Brochures will be prepared with a content and style appropriate to specific target groups. Those focused on health and economic benefits will be distributed at relevant congresses and conferences, and European Commission events. Brochures and posters aimed at patients and patient associations presenting the study objectives, timeline, conduct, information about CVD, polypill, increase of adherence and reduction of events will be available on-line and widely distributed.

A letter of presentation of the SECURE project will be sent to patient associations and to Health Care Authorities to make them aware of the study objectives and arguments for participation.

ARTTIC and CNIC will lead the production of reference documents in English and clinical partners will be responsible for the translation in their country if necessary.

3.3.5 Newsletters

Newsletters will be distributed to relevant stakeholders, such as research funding organisations, professional medical associations, patient groups and other relevant Non-Governmental Organisations (NGOs), at European, national and local levels). The purpose will be to highlight progress of the SECURE programme, key findings and publications, accompanied by relevant educational material, every quarter approximately.

3.4 Events and collaborations

Dissemination will partly take place through the participation in targeted international conferences with poster and podium presentations. SECURE partners have already planned to meet on the occasion of the annual ESC Congress and will attend other events such as:

- The World Congress of Cardiology
- The World Congress on Heart Disease
- National congresses
- The American Heart Association Meeting.

The SECURE consortium will also try to establish cooperation with other projects in the field of cardiovascular prevention and exchanges with standardisation committees.

Towards the end of the project the final results will be presented during the following ESC Congress. ARTTIC and CNIC will organise this presentation thanks to their experience in this field and with the help of the other partners.

4. Partners' role and planned effort

Part n°	Short Name	Coun -try	Fields of competences brought to SECURE	Role regarding dissemination actions throughout the project	Planned Effort in Person Months
1	CNIC	ES	The Spanish National Centre for Cardiovascular Research has extended experience in Clinical trials management thanks to several translational projects performed in the centre. Previously, CNIC led the FOCUS (Fixed-dose Combination Drug for Secondary Cardiovascular Prevention) study, funded under the Seventh Framework Programme.	CNIC will be the central hub for the publication of results, and the facilitator of general information conveyance regarding the results of SECURE, either through their publications, or through specific events either it organises or attends.	16
2	IRFMN	IT	The Mario Negri Institute for Pharmacological Research has long and extensive experience in the coordination of multicentre clinical trials as well as in pharmaco-epidemiological research in the elderly. This includes the activation of large collaborative networks in the National Health Service, which can now count on the permanent collaboration of several Cardiac Departments, representing the overall country. IRFMN was responsible of the coordination in Italy for the FP7 Project FOCUS.	IRFMN will present the Project and disseminate the results through: ▪ IRFMN website: www.marionegri.it and IRFMN internal seminars ▪ An Italian public consumer website, that promotes research activities aimed at developing the participation of citizens and patient groups, to the health decision process: www.partecipasalute.it ▪ The presentation of results at national level (national congresses and meetings of cardiologic and cardiovascular interest) ▪ Investigators' meetings ▪ Press releases at national level ▪ Italian health magazines articles In addition, IRFMN will critically review the reports	6.5

Part n°	Short Name	Coun -try	Fields of competences brought to SECURE	Role regarding dissemination actions throughout the project	Planned Effort in Person Months
				and study articles for important intellectual content and for the final approval of the version to be published.	
3	CHAR	DE	The Centre for Stroke Research Berlin - CSB is one of the Centres at Charité University focussed on clinical and basic research on stroke and on the cerebro-cardiovascular disease complex. It includes a certified Clinical Trial Unit that currently coordinates approximately 40 local and multicentre observational and interventional clinical trials. The Department of Cardiology has long-standing and widely published experience with pathophysiological and clinical trials in chronic illness.	CHAR will contribute to scientific publishing related to the SECURE study and participate in analysing and writing of protocol paper and outcome papers. CHAR will be leading and/or contributing to publications of general results and partial results from (national) subgroups and subsequent analyses. CHAR will be contributing to dissemination of the study protocol and results with abstracts, posters and oral presentations at national and international scientific meetings and conferences.	3
4	UHB	FR	University Hospital of Besançon has already been coordinator for France in several multinational trials. UHB will use the national network of cardiology (FACT) for the communication with the sites of investigation.	UHB, in collaboration with FACT (the French Alliance for Cardiovascular Trials), will be responsible for coordinating the implementation of the SECURE study in the network of French hospitals participating in the trial. UHB will be the link between French investigators and the coordinator of the project, and will disseminate all relevant medical and clinical knowledge to the French centres before and during the trial, through regular communication, newsletters and investigator meetings. Finally, UHB will participate in the writing of the scientific publication that will come out of the SECURE study.	1.5

Part n°	Short Name	Coun -try	Fields of competences brought to SECURE	Role regarding dissemination actions throughout the project	Planned Effort in Person Months
5	UM Wroclaw	PL	The Department of Heart Diseases of Wroclaw Medical University has an extensive experience in designing and conducting research projects and multinational studies, and is a world recognized expert in the field of treatment of chronic and acute heart failure. The Department has specialized structures and qualified staff responsible for project management and assisting with commercialization of generated intellectual property.	UM Wroclaw will review and participate in major SECURE publications. UM Wroclaw will also contribute to dissemination of the study protocol and results with abstracts, posters and oral presentations at national and international scientific meetings and conferences.	10
6	SE	HU	Semmelweis University has over 240 years of tradition of medical education, clinical and preclinical research, supported by their clinical departments and theoretical institutions.	SE will organise a special symposium dedicated to SECURE at the regular meeting of the Hungarian Society of Cardiology taking place every year in May. Information about the SECURE project will also be communicated through SE's website http://vszek.semmelweis.hu/ and on a monthly basis at meetings within the cardiology centre.	2.5
7	GUHP	CZ	General University Hospital in Prague is the principal teaching facility for the First Medical Faculty of Charles University. The two institutions together generate most of the medical research results in the Czech Republic. The Cardiovascular Centre in GUHP provides a complex spectrum of services in cardiology and vascular medicine.	GUHP will organise a special symposium dedicated to SECURE at the regular meeting of the Czech Society of Cardiology taking place every year in May. Information about the SECURE project will also be communicated through GUHP's website http://vfn.cz/ and the complex cardiovascular centre of GUHP (http://kardio.vfn.cz/). In addition, SECURE meetings will be organised on a monthly basis within the complex cardiovascular centre. GUHP will be responsible for coordinating the	18

Part n°	Short Name	Coun -try	Fields of competences brought to SECURE	Role regarding dissemination actions throughout the project	Planned Effort in Person Months
				implementation of the SECURE study in the network of Czech hospitals participating in the trial. In parallel, GUHP will disseminate all relevant medical and clinical knowledge to the Czech centres before and during the trial, through regular communication, newsletters and investigator meetings. GUHP will contribute to the scientific publishing related to the SECURE study and to dissemination of the study protocol and results with abstracts, posters and oral presentations at national and international scientific meetings and conferences.	
8	SERMAS	ES	Servicio Madrileño de Salud is the legal representative of Hospital Clínico San Carlos. Its Cardiology Department is actively involved in several cardiovascular research areas including multicentre clinical trials and self-designed research. The hospital has contributed in the FOCUS FP7 trial, using the CNIC-FERRER polypill.	SERMAS will conduct the trial in Spain together with the Spanish Clinical Research Network (SCReN) platform. Dissemination actions throughout the project will include: investigator meetings at national level, regular newsletters, participation in symposia organisation at national and international meetings, contribution to the scientific communication of results (abstract, poster and oral presentations), drafting/reviewing scientific result papers in close collaboration with CNIC and the SECURE partners.	6
9	LSHTM	UK	The London School of Hygiene and Tropical Medicine's Department of Medical Statistics is a worldwide leader in the profession of medical statistics, with a particular expertise in clinical trials.	LSHTM will carry out the statistical analysis for the trial and will be responsible for the production and dissemination of tables and figures summarising the statistical results of the trial for use in publications and presentations.	2

Part n°	Short Name	Coun -try	Fields of competences brought to SECURE	Role regarding dissemination actions throughout the project	Planned Effort in Person Months
10	ARTTIC	FR	ARTTIC is specialised in the provision of advice and practical assistance in all aspects of international R&D collaborations, including in services helping to successfully disseminate and exploit project results.	ARTTIC will coordinate information dissemination and event management, including logistics for workshops, public website and preparation of dissemination material, etc.	10
11	Ferrer	ES	Ferrer is an international privately-held pharmaceutical company, with a presence in more than 90 countries. They establish strategic alliances with hospitals, biotech companies, public research bodies, academic institutions and other pharmaceutical companies all over the world. Their expertise encompasses the discovery and development of active medicinal substances, diagnostics, new pharmaceutical forms, drug re-profiling, cell therapy, personalized medicine, new therapeutic targets, vaccines, galenical formulations, food and feed additives and optimized industrial processes. In SECURE they are responsible for providing the Trinomia® medication.	Ferrer will review and participate in all SECURE publications. Ferrer will also be attending specific SECURE events.	2.8

In addition to the planned effort, ARTTIC also has a dedicated budget for the public website and production of dissemination material.

5. Conclusion

This dissemination plan will be useful for the implementation of dissemination and communication activities throughout the project. A first activity has been implemented in the form of the SECURE public website (see Deliverable D2.1).

The SECURE project results will be of high value interest to a wide range of stakeholders, in particular for the Cardiology and Cardiovascular Professional Societies and Associations but also in general for stakeholders within Patients and their Associations, Health Care Professionals, comprising Physicians and Nurses, and Health Care Authorities at European, National, Regional and individual Hospital levels. The SECURE consortium has defined this dissemination plan to make these stakeholders aware of the objectives of SECURE, to update them on progress of the project and to share the results with them.