

# FOCUS



## Final Report

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# 1. Final Publishable Summary Report

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## 1.1 Executive Summary

# FOCUS

**Fixed Dose Combination Drugs For Secondary Cardiovascular Prevention**

The FOCUS (Fixed-dose Combination Drug for Secondary Cardiovascular Prevention) study was a 4-year "Small or Medium-Scale Focused Research Project" funded under the Seventh Framework Programme of the European Commission. It consisted in a clinical trial aimed at testing a fixed dose combination (FDC) pill for secondary prevention of cardiovascular diseases in developing countries and in the EU.

The FOCUS study, coordinated by the National Centre for Cardiovascular Research in Spain (CNIC), comprised two subsequent phases. Phase 1 was an observational study which aim was to analyse patients' adherence to treatment and identify clinical and socioeconomic factors responsible for the lack of adherence. Phase 2 was a randomised clinical trial testing the effect of a FDC, the CNIC-FS-FERRER polypill, containing three components of well demonstrated efficacy – acetylsalicylic acid (ASA) 100 mg, simvastatin 40 mg and ramipril 2.5, 5 or 10 mg – as compared to standard treatment (the three drugs provided separately). The objective was to compare adherence to treatment and control of cardiovascular risk factors between the two treatments.

FOCUS was implemented by a consortium comprising partners from Europe and South America: it was conducted in a variety of economic, social, cultural and geographic settings, including two EU countries (Spain, Italy) and three South American countries (Paraguay, Argentina, Brazil) that are lower-middle or upper-middle income developing countries. The clinical research proposed in FOCUS was performed through collaboration among renowned researchers from three major European institutions involved in translational and clinical research, one important partner from the pharmaceutical industry, and a highly experienced academic research organisation from Argentina. Moreover, cooperation was further promoted by the participation in FOCUS of two important scientific organisations in the consortium, the World Heart Federation (WHF) and the Argentine Federation of Cardiology (FAC).

The results of FOCUS were presented at the European Society of Cardiology (ESC) congress on September 2<sup>nd</sup> 2014 and published in the Journal of the American College of Cardiology (JACC), what shed further light on the relationship between a polypill strategy and adherence. For secondary prevention following AMI, younger age, depression, and a complex drug treatment plan are associated with lower medication adherence. Meanwhile, adherence is increased in patients with higher insurance coverage levels and social support. In summary, compared with the three drugs given separately, the use of a polypill strategy significantly increases medication adherence for secondary prevention following an acute myocardial infarction (AMI). The project also published recommendations for the use of the polypill to improve patient adherence to treatment and access to cardiovascular prevention medication, available on FOCUS public website.

## 1.2 Description of the Project Context and Objectives

The principal objective of FOCUS was to develop and test a Fixed-dose combination (FDC) pill for secondary cardiovascular prevention and to evaluate its potential benefit as a component of a cost-effective, globally available and comprehensive treatment strategy. The findings and conclusions obtained in FOCUS have allowed the drafting of recommendations that provide useful guidance and serve as a reference framework for all stakeholders - pharmaceutical companies, clinicians, policy makers and international organisations - involved in tackling major challenges related to secondary prevention and treatment of chronic diseases in developing countries and beyond.

The specific objectives of the FOCUS project were:

1. To demonstrate that better knowledge of factors responsible for an inappropriate use of secondary cardiovascular prevention drugs and of factors related to poor treatment adherence will help to design new strategies for prevention and disease treatment
2. To prove that an FDC pill therapy is effective in controlling various cardiovascular risk factors
3. To show that - compared to taking several drugs separately - an FDC pill results in reductions in inappropriate prescribing, treatment complexity and lack of adherence, and thereby demonstrate that an FDC pill improves secondary prevention in coronary patients.

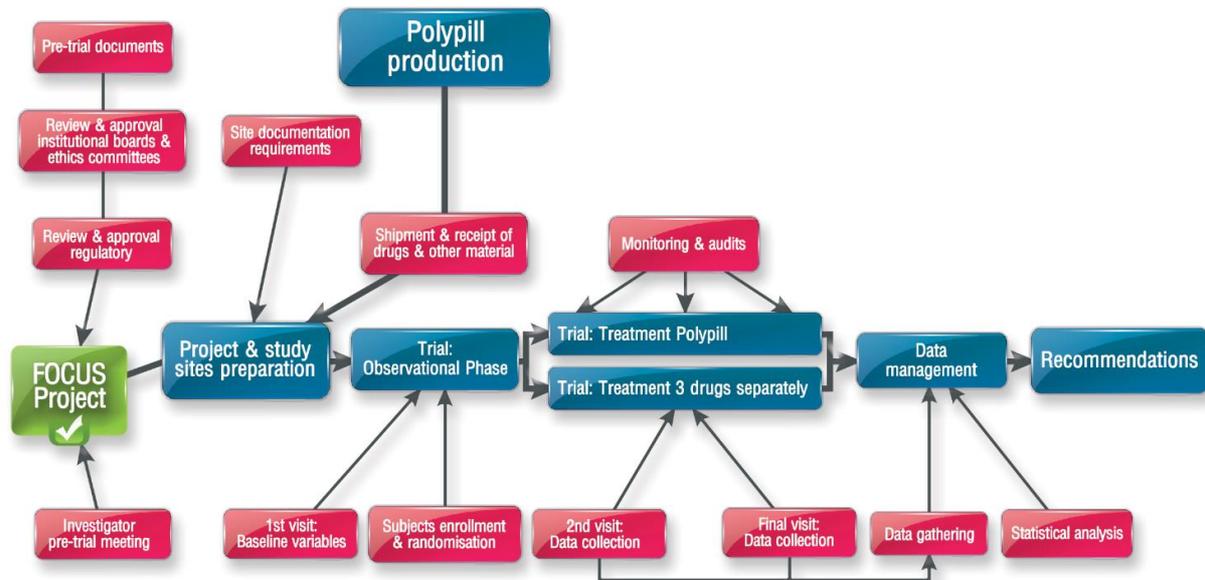
The main hypotheses of the project were:

1. Poor accessibility to medical care and lack of treatment affordability preclude adequate cardiovascular prevention not only in middle to low-income countries, but also in the lowest economic sectors of rich countries. In addition, treatment complexity determines inappropriate prescription and lack of medication adherence. We consider that all these factors should be studied in a variety of countries, cultural settings and health systems in order to establish to what extent they are responsible for poor risk factor control.
2. Strategies that simplify treatment regimens but still provide the required interventions improve patients' management and adherence. We consider that an FDC including three components with well demonstrated efficacy improves secondary prevention in coronary patients by reducing complexity of treatment and lack of adherence.

To test these hypotheses the FOCUS project performed a study including two phases that has been carried out in 25 sites in three developing countries in South-America and in 38 sites in Europe and has involved 2118 (Phase 1) and 722 (Phase 2) post-MI patients, respectively:

- **Phase 1** was a descriptive, non-interventional study. Its aim is to provide a comprehensive analysis of potential factors precluding adequate secondary prevention, including Health system characteristics, drug affordability and availability, as well as patient characteristics.
- **Phase 2** was an interventional, randomised trial with prospective economic evaluation. It was organised as a two arm, randomised, parallel, multinational study. Patients completing phase 1, and fulfilling inclusion/exclusion criteria, were included in phase 2. Patients were randomised to receive an FDC of ramipril, simvastatin and acetilsalicylic acid, or the three medications separately.

The following figure gives an overview of the scientific approach and workflow of FOCUS.



### 1.3 Description of the main S&T Results/Foregrounds

The main results of FOCUS are the following:

- The proof of concept of the efficacy and efficiency of an FDC pill for secondary cardiovascular prevention and treatment over traditional therapies
- New knowledge about and a better understanding of socio-economic factors that impact the adherence to treatment and efficiency of healthcare for cardiovascular diseases
- Knowledge about safety and tolerability of an FDC pill for secondary cardiovascular prevention
- Data about different factors (socio-demographic, economic and clinical) related to inadequate secondary prevention in populations with different health systems and socioeconomic characteristics
- A data base of the anonymised clinical data generated in the clinical trials conducted with a large cohort of post-MI patients from different countries
- Results of the statistical processing of the accumulated clinical data and analysis of factors that condition treatment adherence and efficiency
- Recommendations on how to address major challenges related to effective secondary cardiovascular prevention – adherence and access to treatment

The successful completion of FOCUS will pave the way for making available and affordable secondary cardiovascular prevention medication to a huge number of patients in developing and developed regions. The results of the project will be widely disseminated to promote rapid adoption of the FDC concept for secondary cardiovascular prevention and to encourage new RTD initiatives investigating the FDC concept for other therapies. FOCUS will thereby contribute to addressing a major health issue, reducing human suffering and avoiding a large number of deaths.

## 1.4 Potential impact

### 1.4.1 Major impacts

#### Advancement of the application of evidence-based medicine in Europe and in developing countries

FOCUS will help to advance the application of evidence-based medicine in Europe and worldwide. FOCUS will provide the strongest evidence for therapeutic interventions, having conducted a two-phase clinical trial consisting of an Observational Study followed by a Randomized Trial. Phase 1 was aimed at understanding the factors that determine inappropriate prescription for secondary cardiovascular prevention and poor adherence to treatment; Phase 2 was aimed at testing an FDC pill for secondary prevention of CVD in particular, and the concept of FDC treatments for chronic diseases in general.

The trial has been designed to obtain the data required for analysis, and its outcomes will be directly applicable to clinical practice in both developed and developing countries. FOCUS will significantly advance the application of evidence-based medicine in clinical practice in at least two ways. First, it has **tested a low-cost pill for treatment of the world's major chronic disease**. Second, it will produce **recommendations for a better use of this improved medication** that will promote equitable access to this treatment, especially in resource-poor and developing countries.

FOCUS has been implemented by a consortium comprising partners from Europe and South America and was conducted in a variety of economic, social, cultural and geographic settings, including two EU countries (Spain, Italy) and three South American countries (Paraguay, Argentina, Brazil) that are lower-middle or upper-middle income developing countries according to World Bank classification. The industrial partner in FOCUS is strongly committed to commercialise the FDC pill at an affordable "social" price, a commitment facilitated by the fact that the FDC pill to be tested in FOCUS is a drug combination based on cheap generic compounds that does not require any time-consuming and expensive basic and experimental research. The introduction of a low-price FDC pill will be associated with additional advantages for national health programmes, particularly in resource-poor and developing countries, for example concerning procurement, handling and supply. The FDC pill will therefore represent an additional and substantial cost saving both for the individual patient and for the national health systems; this aspect will facilitate the widespread application of the FDC pill treatment in these countries.

#### Improved use of clinical research findings in clinical diagnosis and treatment; improved patient self-management of disease

Cardiovascular diseases are the main cause of mortality and disability worldwide. In Europe, they are responsible for half of all deaths, causing nearly 4.3 million deaths per year – of which over 2 million deaths accounted for within the 28 member states. Total EU costs for treatment of CVD come to nearly €110 billion per year, representing ~10% of the total healthcare expenditure.

In developing countries, in absolute numbers more people die from non-communicable conditions, including CVD, than in the developed world. It is estimated that coronary heart disease, stroke and diabetes together cause a loss of 0.1% of the gross domestic product in low- and middle-income developing countries, imposing an important additional financial burden to these already weak economies. Taking into consideration the increasing prevalence of cardiovascular disease risk factors, CVD burden is expected to increase significantly over the coming years, to the extent that by 2020 about 90% of the anticipated annual 10 million CVD deaths worldwide are expected to occur in developing countries.

The main aim of FOCUS is to translate clinical research findings directly into practice by developing improved medication for the prevention of cardiovascular diseases and by preparing recommendations for the better use of this medication. **The most effective strategy for curbing cardiovascular diseases is prevention**. For Europe, it has been estimated that an adequate use of

secondary preventive medication (three-drug regimen) could avoid 120,000 cardiovascular events every two years. A recent study by Kahn et al concluded that if all individuals who are candidates for cardiovascular prevention measure in the USA received appropriate intervention **MI could be reduced by 60% and stroke by 30%**. Even with adjustments for incomplete performance, compliance and effectiveness, more than 35% of MI and 20% of strokes could be prevented. The study further concluded that all cardiovascular prevention interventions are cost-effective in different health-system and economic settings, with a cost per QALY below \$ 50,000, the arbitrary but accepted threshold.

The most significant component of prevention costs is the medication, and consequently this is where the greatest savings can be made. This is an issue that will be addressed by the FDC pill. The issue of medication cost is especially critical in low-income countries. The WHO considers interventions to be cost-effective if they have "incremental cost-effectiveness ratios" (\$/QALY) less than three times the gross national income per capita. Gaziano et al. calculated that the ICER of a four-drug secondary prevention regimen ranged between \$306 and \$388 in areas of Asia and South America, being in all cases cost-effective. Again the FDC pill may improve this parameter.

Inadequate prevention is partly due to poor treatment adherence, and this has serious consequences since it translates into increased morbidity and mortality. At least 10% of all hospitalizations are associated with non-adherence with medication. Non-adherence with treatment can also lead to additional diagnostic and therapeutic procedures that may be costly and hazardous. Improvement of adherence by means of an evidence-based FDC pill would reduce the burden of disease. The cost and health effects of lack of adherence in secondary cardiovascular prevention has been analysed by Lim et al. The authors concluded that *"If long-term adherence was 40% in those with existing disease and 20% in those without existing disease then the cumulative number of deaths averted would be reduced to 12.6 million. If long-term adherence was 80% in those with existing disease and 60% in those without disease, then the cumulative number of deaths averted would increase to 23.1 million."* Therefore it seems critical to understand and modify factors that determine poor compliance with treatment. From the data collected in two European and three developing countries, FOCUS will provide valuable information about the socio-economic factors that determine inappropriate prescribing for secondary cardiovascular prevention and treatment adherence. Knowledge about these factors will allow the consortium to prepare recommendations for improved use of medication for patients with ischemic heart disease in a wide variety of economic and social settings.

## Improved patient self-management of disease

The FDC concept is expected to lead to improved patient self-management because of the **easier management of the medication**. It will be easier for patients to comply with a single medication per day rather than a combination of different pills. Also, a single pill combining several medications reduces the risk of miss-management. This will be a major factor for improving patient self-management and adherence in developing countries, but is also relevant for other countries, especially for disadvantaged social groups or regions, the less educated, and the elderly. This last consideration is important in the context of increasing life expectancy. Improved adherence due to easier medication management will reduce the risk of complications and simplify patient follow-up. It will reduce the frequency of visits, improve the level of patient self-management and reduce stress and complications, thereby increasing the efficiency of healthcare whilst reducing its cost. This will be a major benefit not only for the patients but also for their families.

In conclusion, FOCUS will directly contribute to the improved use of clinical research findings in treatment as well as patient self-management of cardiovascular diseases. FOCUS will thereby address a major health issue and, if successful, will contribute to reducing human suffering, improving quality of life, and to avoiding a large number of deaths.

## Enhanced cooperation between researchers in Europe and other geographic regions to promote integration and excellence of European research

Cooperation between researchers in Europe and other regions has been enhanced on various levels and will continue after the project end. The clinical research proposed in FOCUS was performed through collaboration among renowned researchers from three major European institutions involved in translational and clinical research, one important partner from the pharmaceutical industry, and a highly experienced academic research organisation from Argentina. Moreover, cooperation was

further promoted by the participation in FOCUS of two important scientific organisations in the consortium, the FAC and the WHF. These professional organisations, one national and one international, combine the strengths of the medical and public health communities. Both federations support international research, professional and public education, and community programmes related to cardiology. Through their more than 200 member organisations, societies and delegations, these organisations connect the entire global cardiology community, and thus represent the ideal platform for further enhancing cooperation between Europe and other regions, and for the promotion of European excellence in research.

Finally, cooperation between researchers was enhanced by the incorporation of internationally renowned experts on the Scientific and Ethics Advisory Board (FSAEB) that was established for FOCUS. The FSAEB was composed of scientists and other stakeholders from international, independent organisations and its role was to advise the consortium on research policy in order to ensure optimal applicability of the project results. The members of the FSAEB has provided additional expertise to the consortium and an unbiased external view on the project strategy and performance.

## 1.4.2 Dissemination activities and exploitation of results

Throughout the project, the FOCUS study has been presented at various events in the field of cardiovascular research. The final results were then presented at the Congress of the European Society of Cardiology (ESC) on 2 September 2014. This congress is one of the leading international events in cardiology worldwide and the largest medical meeting in Europe.

In addition, the recommendations of the project were included in the final deliverable D8.1, which is available on the public website. The following standard disclaimer will be included in that report and in any related publication: "The sole responsibility for the content of this report lies with the authors. It does not necessarily reflect the opinion of the European Union. The European Commission is not responsible for any use that may be made of the information contained therein."

The results of FOCUS research have a strong exploitation potential: a better understanding of the factors conditioning adherence and access to secondary cardiovascular prevention medication will open the way for a successful commercialisation of such medication. This directly and particularly concerns the industrial partner FERRER, but indirectly also the academic and clinical partners.

The industrial partner can expect important business opportunities from FOCUS. The market potential is very significant world-wide. It has been calculated that the number of potential candidates for cardiovascular FDC treatment is close to 100 million people in western countries and Japan, and more than 170 million people in middle- and low-income countries, with a potential market above €1 billion per year. Public support of the FOCUS project will strengthen the position of Europe in this field as regards the expertise of the scientists and the competitiveness of the European pharmaceutical industry, who will gain an advance on the international competition. The return-on-investment resulting from this successful cooperation will encourage the establishment of further public-private partnerships in health-related RTD projects and thereby strengthen the innovative capacity of European research institutes and industry.

Despite the potentially large business opportunities that can be anticipated, the FDC pill that will be tested in FOCUS has been conceived from the outset as a **secondary prevention therapy at an affordable "social" price for patients, especially in low-income countries**. The pharmaceutical partner in FOCUS is strongly committed to making the drug available at a low price and to making the medication widely available in low- and middle-income countries. This commitment is facilitated by the fact that this FDC pill is a drug combination based on three cheap generic compounds. The cost of generics has decreased steadily in recent years; and the prices of some off-patent, generic cardiovascular drugs have decreased by as much as 25% in the last decade. As a consequence, the cost of raw materials necessary for the manufacturing of a one-month supply of the FDC pill for FOCUS is less than €2. Since raw materials represent a major component of the total cost of medication, it is anticipated that this FDC pill will be available at a social price in low- and middle income countries. Other facts, such as the lower costs related to the distribution of a FDC pill, for example, will also contribute to a lower, more affordable price.

Apart from the commercial exploitation, the researchers involved in FOCUS can expect a return-on-investment through strengthened recognition as leading experts thanks to publication of FOCUS research results.

As there have been no applications for patents, trademarks or registered designs and no exploitable foreground in FOCUS, no Intellectual property Rights (IPR) issues have been identified.

Specific individual plans for exploitation of project result are summarised below:

<b>Partner</b>	<b>Planned use of project results</b>
CNIC	Further activities in innovative cardiovascular diseases research and the development of innovative therapies; scientific publications based on the project results. Further positioning of CNIC as a leader of translational cardiovascular research in Europe.
IRFMN	Take-up of the project results in further pharmacological and biomedical research and education activities; promotion of project results for take-up in clinical practice in the network of associated clinical institutions.
DAMIC	Promotion of the FDC therapeutic approach and FOCUS recommendations in clinical practice in Latin America and beyond; further clinical studies and international RTD collaborations for accessible and efficient healthcare in South-America.
FCRB	Take-up of the project results in further academic clinical research; promotion of project results and FOCUS recommendations for take-up in clinical practice in Europe.
FAC	Dissemination of the project results to cardiologists in Latin America and beyond to accelerate take-up of the FDC benefits and FOCUS recommendations in medical practice.
WHF	Global dissemination of the project results to accelerate take-up of the FDC benefits and recommendations of FOCUS in medical practice.
ISCIH	Take-up of the project results in further public health studies and promotion of project results for take-up in clinical practice.
FERRER	World-wide commercialisation of an FDC pill for secondary cardiovascular prevention at an affordable "social" price.

## 1.5 FOCUS Partners and Contact

### FOCUS Coordinator

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## 2. Use and Dissemination of Foreground

### 2.1 Section A

#### 2.1.1 List of Scientific Publications

No	<a href="#">DOI - Permanent identifier (if available)</a>	Title	Author(s)	Title of the periodical or the series	Volume/ Issue	Publisher	Place of publication	Date of publication	URL	Relevant pages	Open access is/will be provided to this publication
1	<a href="http://dx.doi.org/10.1053/j.semtcvs.2011.05.005">10.1053/j.semtcvs.2011.05.005</a>	Polypill and Global Cardiovascular Health Strategies	Ginés Sanz , Valentin Fuster	Seminars in Thoracic and Cardiovascular Surgery	Vol. 23/Issue 1	W.B. Saunders Ltd	United Kingdom	01/03/2011	<a href="http://linkinghub.elsevier.com/retrieve/pii/S1043067911000633">http://linkinghub.elsevier.com/retrieve/pii/S1043067911000633</a>	24-29	No
2	<a href="http://dx.doi.org/10.1016/j.recesp.2011.02.027">10.1016/j.recesp.2011.02.027</a>	Compuestos de dosis fija en la prevención secundaria de la cardiopatía isquémica	Valentín Fuster , Ginés Sanz	Revista Espanola de Cardiologia	Vol. 64	Ediciones Doyma, S.L.	Spain	01/07/2011	<a href="http://linkinghub.elsevier.com/retrieve/pii/S0300893211006105">http://linkinghub.elsevier.com/retrieve/pii/S0300893211006105</a>	3-9	No
3	<a href="http://dx.doi.org/10.1016/j.ahj.2011.08.012">10.1016/j.ahj.2011.08.012</a>	The Fixed-dose Combination Drug for Secondary Cardiovascular Prevention project: Improving equitable access and adherence to secondary cardiovascular prevention with a fixed-dose combination drug. Study design and objectives	Ginés Sanz , Valentin Fuster , Luis Guzmán , Antonio Guglietta , Joan Albert Arnáiz , Felipe Martínez , Antonio Sarria , Maria Carla Roncaglioni , Kathryn Taubert	American Heart Journal	Vol. 162/Issue 5	Mosby Inc.	United States	01/11/2011	<a href="http://linkinghub.elsevier.com/retrieve/pii/S0002870311006296">http://linkinghub.elsevier.com/retrieve/pii/S0002870311006296</a>	811-817.e1	Yes

No	<a href="#">DOI - Permanent identifier (if available)</a>	Title	Author(s)	Title of the periodical or the series	Volume/ Issue	Publisher	Place of publication	Date of publication	URL	Relevant pages	Open access is/will be provided to this publication
4	<a href="http://dx.doi.org/10.1038/nrcardio.2013.157">10.1038/nrcardio.2013.157</a>	Prevention: Polypills for cardiovascular prevention: a step forward?	Ginés Sanz , Valentin Fuster	Nature Reviews Cardiology	Vol. 10/Issue 12	Nature Publishing Group	United Kingdom	08/10/2013	<a href="http://www.nature.com/doi/10.1038/nrcardio.2013.157">http://www.nature.com/doi/10.1038/nrcardio.2013.157</a>	683-684	No
5	<a href="http://dx.doi.org/10.1016/j.cja.2014.02.016">10.1016/j.cja.2014.02.016</a>	Evolution of the Polypill Concept and Ongoing Clinical Trials	Jose M. Castellano , Gines Sanz , Valentin Fuster	Canadian Journal of Cardiology	Vol. 30/Issue 5	Pulsus Group Inc.	Canada	01/05/2014	<a href="http://linkinghub.elsevier.com/retrieve/pii/S0828282X1400110X">http://linkinghub.elsevier.com/retrieve/pii/S0828282X1400110X</a>	520-526	No
6	<a href="http://dx.doi.org/10.1016/j.jacc.2014.06.009">10.1016/j.jacc.2014.06.009</a>	A Polypill Strategy to Improve Global Secondary Cardiovascular Prevention	José M. Castellano , Ginés Sanz , Antonio Fernandez Ortiz , Ester Garrido , Sameer Bansilal , Valentin Fuster	Journal of the American College of Cardiology	Vol. 64/Issue 6	Elsevier USA	United States	01/08/2014	<a href="http://linkinghub.elsevier.com/retrieve/pii/S0735109714028988">http://linkinghub.elsevier.com/retrieve/pii/S0735109714028988</a>	613-621	No
7	<a href="http://dx.doi.org/10.1016/j.recesp.2014.05.002">10.1016/j.recesp.2014.05.002</a>	Policomprimido: ¿quimera o realidad? (Polypill: Chimera or Reality?)	Ginés Sanz , José M. Castellano , Valentín Fuster	Revista Espanola de Cardiologia	Vol. 67/Issue 9	Ediciones Doyma, S.L.	Spain	01/09/2014	<a href="http://linkinghub.elsevier.com/retrieve/pii/S0300893214003066">http://linkinghub.elsevier.com/retrieve/pii/S0300893214003066</a>	689-692	Yes

## 2.1.2 List of Dissemination activities

### Period 1

Acti vity no.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
1	Articles published in the popular press	CNIC	Article from Ginés Sanz and Valentin Fuster mentioning FOCUS in FAC Journal "Cardiovascular disease prevention: an unresolved issue"	01/07/2010	Argentina	Scientific community (higher education, Research)		Argentina
2	Publication	FAC	Article about FOCUS in FAC Journal 2011, Edition 1, January-April	01/01/2011	Argentina	Scientific community (higher education, Research)	2500	Argentina
3	Web sites/ Applications	FAC	Banner	01/02/2011	Argentina	Scientific community (higher education, Research)		Worldwide
4	Articles published in the popular press	FAC	Article in journal Edición Nacional	01/03/2011	Argentina	Civil society	95000	Argentina
5	Publication	FAC	Presentation of FOCUS in Newsletter: NotiFAC Especial	10/03/2011	Argentina	Scientific community (higher education, Research)	5000	Argentina
6	Publication	FAC	Article about FOCUS in Newsletter: NotiFAC	17/03/2011	Argentina	Scientific community (higher education, Research)	5000	Argentina
7	Presentations	DAMIC	New challenges in Cardiovascular Prevention	29/04/2011	Lima, Perú	Scientific community (higher education, Research)	300	Perú - Peruvian Congress of Cardiology

Acti vity no.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
8	Web sites/ Applications	FAC	Page about FOCUS on FAC Website	01/05/2011	Argentina	Scientific community (higher education, Research)		Argentina
9	Web sites/ Applications	FAC	Communication on Twitter about FOCUS	10/05/2011	Argentina	Scientific community (higher education, Research)	100	Argentina
10	Presentations	DAMIC	Cardiovascular Prevention at National Congress of Cardiology of Argentine Cardiology Federation (FAC)	20/05/2011	Córdoba, Argentina	Scientific community (higher education, Research)	400	Argentina, Brasil, Paraguay
11	Flyers	ARTTIC	FOCUS leaflet	23/06/2011	France	Scientific community (higher education, Research) - Civil society		International
12	Presentations	FAC	International Symposium Cardiovascular Prevention - FAC Federated Societies	29/07/2011	Rosario, Argentina	Scientific community (higher education, Research)	700	Argentina
13	Presentations	DAMIC	Cardiovascular Prevention (Internal Medicine Seminar)	19/08/2011	Córdoba, Argentina	Scientific community (higher education, Research)	40	Argentina
14	Organisation of Conference	FAC	"New Issues in CV Prevention" Audiovideo tele conferences with FAC Societies in Provinces	01/09/2011	Audiovide o tele conferenc es with FAC Societies in Provinces	Scientific community (higher education, Research)	350	Argentina
15	Presentations	DAMIC	"Cardiovascular Prevention", Congress of Argentine Society of Cardiology	01/10/2011	Buenos Aires, Argentina	Scientific community (higher education, Research)	700	Argentina

Acti vity no.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
16	Presentations	DAMIC	"Cardiovascular Prevention", Argentine Society of Sport Medicine Symposium	01/11/2011	Córdoba, Argentina	Scientific community (higher education, Research)	200	Argentina
17	Presentations	DAMIC	"Cardiovascular Prevention" at Argentine Lipid Society	25/11/2011	Buenos Aires, Argentina	Scientific community (higher education, Research)	500	Argentina
18	Presentations	DAMIC	"Interventions in the SRAA and Cardiovascular Prevention" Chilean Congress of Cardiology	01/12/2011	Viña del Mar, Chile	Scientific community (higher education, Research)	450	Chile
19	Organisation of Conference	FAC	"Cardiovascular Prevention" Audiovideo teleconference from La Plata National University Auditorium	01/12/2011	La Plata City - Buenos Aires State	Scientific community (higher education, Research)	1000	Argentina

Period 2

Activity no.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
20	Oral presentation to a scientific event	FAC	National Congress of Cardiology of Argentine - lectures and interviews about FOCUS	29/05/2012	Salta, Argentina	Scientific community (higher education, Research)	450	Argentina, Brazil and Paraguay
21	Oral presentation to a scientific event	WHF	Presentation at the Global Summit on Combination Polypharmacy for Cardiovascular Disease	25/09/2012	Hamilton, Canada	Scientific community (higher education, Research)	80	Worldwide
22	Oral presentation to a scientific event	DAMIC	Investigator Initiative Studies	11/10/2012	Buenos Aires, Argentina	Scientific community (higher education, Research)	250	Argentina
23	Oral presentation to a scientific event	DAMIC	National Congress on Stress	12/10/2012	Cordoba, Argentina	Scientific community (higher education, Research)	300	Argentina
24	Oral presentation to a scientific event	DAMIC	Internal Medicine Symposium	25/10/2012	Cordoba, Argentina	Scientific community (higher education, Research)	400	Argentina
25	Articles published in the popular press	FAC	Article about FOCUS in Newsletter: NotiFAC Especial	03/05/2013	Argentina	Scientific community (higher education, Research)	5000	Argentina
26	Oral presentation to a scientific event	FAC	National Congress of Cardiology of Argentine - lectures and interviews about FOCUS	22/05/2013	Rosario, Argentina	Scientific community (higher education, Research)	450	Argentina

Period 3

Acti vity no.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
27	Oral presentation to a scientific event	DAMIC	Perspectives on Polypill - X Annual Scientific Meeting. Argentina Society of Lipids	13/09/2013	Buenos Aires, Argentina	Scientific community (higher education, Research)	500	Argentina
28	Oral presentation to a scientific event	CNIC	Presentation of FOCUS and polypill at FAC Congress & FOCUS Investigators Meeting	04/10/2013	Rosario, Argentina	Scientific community (higher education, Research)		Latin American countries
29	Articles published in the popular press	FAC	Article about FOCUS in Newsletter: NotiFAC Especial	08/10/2013	Argentina	Scientific community (higher education, Research)	5000	Argentina
30	Oral presentation to a scientific event	DAMIC	Symposium Challenges and Opportunities in Cardiovascular Prevention: From Aspirin to Polypill, XXIV Interamerican Congress of Cardiology / XXXIX Argentine Congress of Cardiology	18/10/2013	Buenos Aires, Argentina	Scientific community (higher education, Research)	800	Latin American countries
31	Oral presentation to a scientific event	DAMIC	FOCUS Investigator Meeting	18/10/2013	Buenos Aires, Argentina	Scientific community (higher education, Research)	50	Argentina, Brazil and Paraguay
32	Articles published in the popular press	FAC	Article about FOCUS in Newsletter: NotiFAC	21/10/2013	Argentina	Scientific community (higher education, Research)	5000	Argentina
33	Oral presentation to a scientific event	DAMIC	Round Table in Cardiovascular Prevention - 10th Global Cardiovascular Clinical Trialists Forum CVCT 2013	06/12/2013	Paris, France	Scientific community (higher education, Research)	500	International

Acti vity no.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
34	Articles published in the popular press	FAC	Article about FOCUS in FAC Journal 2014, Edition 1, January-April	01/01/2014	Argentina	Scientific community (higher education, Research)	2500	Argentina
35	Oral presentation to a scientific event	DAMIC	Secondary Cardiovascular Prevention - National University of Córdoba	14/03/2014	Cordoba, Argentina	Scientific community (higher education, Research)	150	Argentina
36	Oral presentation to a scientific event	DAMIC	Polypill in Hypertension - XXI Congress of Arterial Hypertension - Argentine Society of Arterial Hypertension	12/04/2014	Buenos Aires, Argentina	Scientific community (higher education, Research)	300	Latin American countries
37	Organisation of Conference	WHF	World Congress of Cardiology, several talks about the polypill	05/05/2014	Melbourne, Australia	Scientific community (higher education, Research)	75	Global
38	Oral presentation to a scientific event	DAMIC	Round Table in Cardiovascular Prevention - V International Congress of Internal Medicine	07/05/2014	Cordoba, Argentina	Scientific community (higher education, Research)	500	Latin American countries
39	Organisation of Conference	WHF	Cardiovascular Combination Pharmacotherapy Global Summit, presentation of FOCUS	08/05/2014	Melbourne, Australia	Scientific community (higher education, Research)	50	Global
40	Oral presentation to a scientific event	DAMIC	Round Table on Local Guidelines of CHD and Polypill in Cardiovascular Prevention - XXXII National Congress of Cardiology - Argentine Federation of Cardiology	29/05/2014	Mendoza, Argentina	Scientific community (higher education, Research)	500	Latin American countries
41	Oral presentation to a scientific	DAMIC	Polypill in Hypertension - Chilean Society of Arterial Hypertension	26/06/2014	Santiago de Chile,	Scientific community (higher education,	200	Chile

Acti vity no.	Type of activities	Main leader	Title	Date	Place	Type of audience	Size of audience	Countries addressed
	event				Chile	Research)		
42	Oral presentation to a scientific event	CNIC	Presentation of FOCUS results at European Society of Cardiology Congress	02/09/2014	Barcelona, Spain	Scientific community (higher education, Research)		Europe

## 2.2 Section B

### 2.2.1 List of applications for patents, trademarks, registered designs, etc.

There have been no applications for patents, trademarks or registered designs.

### 2.2.2 List of exploitable foreground

There have been no exploitable foreground in FOCUS.

### 3. Societal Implications

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The report covering the wider societal implications of the project, in the form of a questionnaire, including where applicable gender equality actions, ethical issues, efforts to involve other actors and to spread awareness has been answered online.