

PROJECT FINAL REPORT

Grant Agreement number: 305125
Project acronym: ECRAN
Project title: European Communication on
Research Awareness Needs
Funding Scheme: CSA
Period covered: from 01/09/2012 to 31/08/2014

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EUROPEAN COMMUNICATION ON
RESEARCH AWARENESS NEEDS

GRANT AGREEMENT NUMBER 305125

Final report

01 September 2012 – 31 August 2014



CONTENTS

1. Final publishable summary report	4
1.1 Executive summary	4
1.2 Description of project context and objective	5
1.3 Work performed and main results	7
1.4 The potential impact and dissemination	10
1.5 Dissemination	13
1.5.1 ECRAN logo	13
1.5.2 ECRAN website	14
1.5.3 ECRAN tools	15
1.5.4 ECRAN animated film	16
1.5.5 ECRAN poster	17
1.5.6 ECRAN brochure	18
1.6 Consortium and acknowledgments	19
2. Use and dissemination of foreground	20
A2: List of dissemination activities	21
3. Report on societal implications	38

1. Final publishable summary report

1.1 Executive summary

The ECRAN - European Communication on Research Awareness Needs - project has been designed to develop a portfolio of open educational resources for the general population about the challenges raised by independent clinical research. It has been designed to support the strategy of the European Commission to fund independent (investigator-driven) multinational clinical trials. Independent clinical trials are considered of critical importance for improving the effectiveness, safety, and cost-effectiveness of health care. The target audiences of the ECRAN project were primarily patients and citizens, but also policymakers, healthcare professionals, researchers, and journalists. All the ECRAN materials have been developed to be simple, not technical, readable for all the targets, and easy to be used in the clinical practice.

At the beginning of the ECRAN project an online survey on Learning Needs Assessment has been carried out on the public's needs, the results have allowed to guide the development of ECRAN tools and materials. All the material and tools have been developed under Creative Common License and are freely available at the website of the project, <http://www.ecranproject.eu>.

The materials and tools have been translated to cover 3/4 of the European population.

The main results obtained by the ECRAN project are:

- A website developed after a revision of the existing websites, in six European languages with some parts in 23 languages. All the tools developed are available on the website.
- An animated film about clinical trials titled “Clinical research matters to you: do you want to know more?”. The film is available in 23 European languages.
- A searchable online dynamic database where have been systematically collected, identified and catalogued communication materials and tools designed to convey the importance of clinical research to the public. The database is searchable in all 23 European languages.
- Two serious/educational games to capture the interest of young European citizens and students. ECRAN Lab and ECRAN Maze are a cross platform games available in six European languages for iPad, Android Tablet and Windows 8.
- A Media section dedicated to journalists to disseminate the contents of the ECRAN project uniformly across countries.
- Interactive sibling websites of Testing Treatments Interactive in six languages. Testing Treatments is a book written for the public addressing many questions related to clinical research of interest for the ECRAN project.
- A revision of existing Wikipedia pages related to clinical trials issues.

Two months before the end of the project the Consortium has been organized a Celebrating event in Luxembourg. This was a joint initiative – ECRAN, ECRIN-ERIC (European Clinical Research Infrastructures Network), ICTD (International Clinical Trials' Day) and CRP (Centre de recherche public) - to promote a transnational communication event on multinational clinical trials with the objective of facilitating better clinical research relevant to the needs of patients and highlight the important role of patients in clinical research.

During the ECRAN project other dissemination activities have been: articles on magazines and newsletters, congresses at local and international level, learning activities, website links, blogs, twitters discussion lists, announce letter to ad hoc mailing lists of consumers and patients associations, distribution of the ECRAN brochure, an Open letter to all European Ministers of Education, European heads of schools, European teachers, and parents. Moreover networks such as ECRIN, Cochrane Consumers Network, PartecipaSalute and European AIDS Treatment Group widely disseminated the ECRAN project.

The ECRAN project has achieved all its goals and now citizens, patients and all people involved in research have valuable tools and material to facilitate the understanding and the participation in clinical research.

1.2 Description of project context and objective

The European Commission funded in 2012 the two-years ECRAN project - European Communication on Research Awareness Needs - to improve the EU citizens' knowledge about clinical research, and to support their participation in independent and multinational clinical trials. ECRAN's principal aim was to inform citizens and patients, but also healthcare professionals, researchers, and journalists, about the importance of independent clinical trials driven by healthcare needs, the need for transparency and optimal use of data, and the importance of multinational cooperation, taking advantage of Europe's population size and diversity.

The ECRAN project has been designed to support the strategy of the European Commission to fund independent (investigator-driven) multinational clinical trials, as a major component of the FP7 cooperation health priority work programme. For the first time in 2011, 152M€ were allocated to 26 independent multinational clinical trials. Simultaneously, through its capacity programme, the Commission supported the development of ECRIN (www.ecrin.org) to provide an infrastructure for multinational clinical trials, initially through FP7 infrastructure funding for its preparatory phase (2008-2011), then through an integrating activity (2012-2015).

Although the concept of randomised trials emerged from academic institutions, clinical trials are now central to the development of innovative health products seeking marketing authorisation from competent authorities. Industry-sponsored pre-licensing trials (commercial trials) account for more than 70% of all the clinical trials on medicinal products in Europe. However, a growing number of clinical trials are conducted independently of manufacturers, thanks to the development of appropriate infrastructures and to the availability of national public and charitable funding. Industry is not interested in investing in these trials, either because the product is already marketed, or because comparative data with alternative interventions is not currently required, or because the potential market is too narrow, or because of lack of other incentives. Until recently, multinational cooperation in independent clinical trials has been restricted by a lack of multinational funding. The FP7 initiative thus represents a major development in this field.

Clinical trials refer to clinical research assessing the benefits and harms of interventions, such as medicinal products, medical devices, and therapeutic procedures such as surgery, physical and psychological therapies. Independent clinical trials are of critical importance for improving the effectiveness, safety, and cost-effectiveness of health care. They also help to establish the relative efficacy of interventions, and thus their position in the therapeutic armamentarium, and they foster affordability for the health services.

Most drug and device clinical trials in Europe and elsewhere are sponsored by the health industry, working in close collaboration with academic investigators and clinicians. These trials are product-oriented, aimed at providing evidence for the benefits of a given health product (does this product merit a marketing authorization?). However, a very large number of clinical research questions are of little or no interest to commercial sponsors, yet they need to be addressed because of their importance in promoting the health of the public and improving diagnosis and therapy for large, medium-sized, and small patient groups. This large number of clinical research questions deals not only with drugs and devices, but also with new biomedical interventions, surgery, physiotherapy, psychology, rehabilitation, training, etc. Such healthcare-oriented research questions (what is the best therapeutic option for this disease, this patient or this group of patients?) are clearly critical for patients, healthcare professionals, healthcare systems, reimbursement policies and payers. They are usually addressed through the initiative of clinical investigators or patient groups. The need to support such independent (investigator-initiated and healthcare-driven) clinical research in addition to commercially-sponsored research has been recognized by the European Science Foundation

(Investigator-Driven Clinical Trials 2009 Implementation of Clinical Research in Clinical Practice 2011), and the European Union.

On the basis of these issues, the ECRAN project has been designed considering that:

- Randomized clinical trials are a milestone of evidence-based medicine, but still citizens don't have enough knowledge and awareness of the importance of this method.
- Even if European Commission is allocating substantial funding to independent, investigator-driven clinical trials, the participation of citizens and patients in clinical research projects is still difficult.
- A pan-European infrastructure for clinical trials (ECRIN) is available to design, coordinate, and facilitate inter-European clinical trialists, but without a shared package of information tools for general population and patients.

The objective of the ECRAN project was to develop a portfolio of open educational resources to communicate key messages to general population - but also healthcare professionals, researchers, policymakers and journalists – about:

- The importance of public understanding of need and basic principles of clinical trials, fostering active involvement of citizens/patients in trials and of their representatives in trial design;
- The need for independent clinical trials, not only on drugs [!], driven by healthcare and patients needs, to optimise strategies, to support evidence-based clinical practice and to reduce healthcare inequalities.
- The need for transparency and optimal use of data to allow their use in analysis and meta-analysis, but also to prevent bias in presenting and analysing results.
- The need for multinational cooperation, taking advantage of Europe's population size, diversity and medical expertise.

Primary target of the ECRAN project: EU citizens, as tax payers, users of healthcare systems, and potential future patients, including school students, to raise awareness of clinical trials; patients and other participants in clinical trials; representatives of patient organizations. To ensure efficient dissemination, all the communication tools developed in the project have been translated and dubbed to reach at least 3/4 of the European citizens.

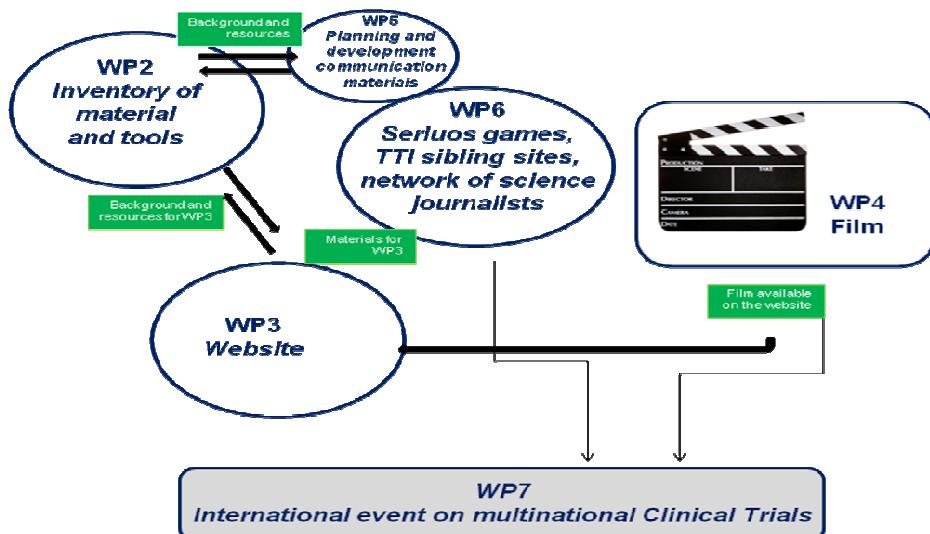
Secondary target of the ECRAN project: Healthcare professionals; health and science policy makers, members of parliaments; members of research ethics committees; communicators, including journalists; and scientific community.

In most of the European countries clinical trials are rarely the subject of debate among citizens or consumers or patients organizations. Still more rarely are the research priorities discussed a priori in an open debate between researchers, clinicians, and patients. The involvement of European citizens in supporting independent clinical trials as a method to lead health care assistance decisions varies among countries. Studies have shown that misconceptions about clinical trials are frequent, and that the level of participation in clinical trials is low. As a consequence, it is important to empower citizens and health consumers on the crucial aspects of clinical research, and increase their awareness of independent clinical trials. The ECRAN project aims to address this situation through a number of concerted activities.

1.3 Work performed and main results

The ECRAN project has achieved all its goals and now citizens, patients and all people involved in research have valuable tools and material to facilitate the understanding and the participation in clinical research.

An overview of the ECRAN project is reported in the figure below. All the material and tools have been developed under Creative Common License and are freely available at the website of the project.



The survey The first step of the ECRAN activities has been to undertake a Learning Needs Assessment, which was integrated into the task of collecting online materials related to understanding clinical trials. A survey of public users of health information to obtain information about the public's need for information on clinical trials was carried out. The survey has been distributed using two main channels: (a) PatientView, an organization that keeps a database of patient groups via whom we were able to email to 20,000 English-speaking patient groups across Europe, and (b) NHS Choices, a website funded by the UK Department of Health, dedicated to informing the public on health issues. A total of 1852 completed the survey. The survey provided a glimpse into the lack of public understanding about how clinical trials are conducted. While the overall reason for conducting such trials may be understood, there is little further understanding of the process.

The online dynamic database A searchable online dynamic database where have been systematically collect, identify and catalogue communication materials and tools that are designed to convey the importance of clinical research to the public. One hundred and eighty one unique online learning resources were identified through English-speaking patient groups, and an additional forty five unique resources through NHS Choices patient website, and seventy nine through ECRAN partner organisations. The database is searchable for resources in all 23 European Languages and it includes open educational resources, websites, videos, books, interactive applications, and others.

The website The ECRAN website (<http://ecranproject.eu>) has been developed after a careful revision of the existing websites, in six languages, with some parts in 23 languages. The website is addressed to the general public, patients and participants in clinical trials as primary targets and to health professionals, policy makers, and communicators, as secondary targets.

It provides plain language information on the project (key topics and messages of the project), access to all the communication material produced, updates and results of the ECRAN project. The style of communication taken into account the primary target, paying a constant attention to plain - matching easiness to precision, as necessary especially when referring to technical/scientific terms - and attractive - friendly and even with direct speech - style. The ECRAN website includes several sections:

- Homepage it includes navigation tools and a presentation of the main sections, the links to ECRAN accounts on Twitter (<https://twitter.com/EcranProject>) and Facebook (<https://www.facebook.com/ecran.project>); in the footer there are the newsletter subscription, badges, survey and contacts.
- “About clinical trials” is a core section of the website and it has been developed as an “on-line book” organized in two levels of titles with a clickable table of contents at the footer of each webpage. This solution offers the opportunity to easily add new contents during the whole life of the website. The following contents have been developed: information about clinical studies (e.g FAQs, tutorial, see WP6); glossaries in different languages selected using the information collected by means of the Inventory of resource and the websites analysis (an ECRAN glossary has not been developed firstly because many good quality glossaries are already available, but also for budget reasons); valuable materials for ECRAN key-messages communication to the public
- “ECRAN film” - dubbed in 23 languages, complete sequence divided in the 8 modules-, “Inventory of resources” with a dedicated searchable online dynamic database, “Serious games”, “Testing Treatments Interactive”
- Media center, section dedicated to journalists
- ECRAN Newsletter
- Links to partners’ or international relevant initiatives on independent and multinational clinical research themes.
- Downloadable badges to facilitate online dissemination.

The final ECRAN website represents a distinct novelty in the European context, in terms of number of languages available and contents or objects.

The animated film One of the most effective ways to convey information, in particular health information, is produce a film. For this reason the ECRAN Consortium decided to produce a film as a flagship of communicative tools, thanks also to the collaboration of RAI the Italian public television service and Studio Bruno Bozzetto. The text of the film was written on the basis of the key words of the project and through some interviews. This text has been translated in a story board, where images were associated with phrases. The story board has been discussed and reviewed among ECRAN partners several times and then the film was produced, first in Italian and in English. The film starts with the story of Scottish naval surgeon James Lind in his determined effort to treat scurvy, set up an experiment cheered today as one of the earliest clinical trial. The dubbing process produced 23 versions of the film. The dubbing process involved professional translators, but also colleagues from different countries and networks (as ECRIN and EATG) that review the text and the first version of the film. Now the film is available and free in 23 official European. Norwegian and Luxembourgish version are also available because two independent research groups decided to invest funds for dub the film in their language.

It is possible to view the whole film (less than 5 minutes) but also have access to the 8 different modules regarding important aspects of clinical research: A clinical trial, Ethics committees, Randomization, Double blinding, Analysing the data, One trial is not enough..., Outcomes have to be important to patients, Some pitfalls of trials.

Serious games To capture the interest of young European citizens and students two serious/educational games have been developed. ECRAN Lab and ECRAN Maze are a cross platform games available in 6 languages for iPad, Android Tablet and Windows 8. According to a conventional classification ECRAN Lab - a game dealing with the 4 phases of clinical trials - belong to action games, which includes ability games, chase, fighting, while ECRAN Maze - a game aimed at improving knowledge and transferring information - belong to puzzle games which include quizzes and labyrinth and are particularly useful in transferring information and knowledge. Since April to June 2014, the ECRAN serious games and, more extensively, the ECRAN project as a whole, were presented to the students of a secondary school in Milan. This activity represented a good opportunity to test communication materials on a sample, even of limited size, of young European citizens, one of the main target of the ECRAN project.

Media Section A section dedicated to journalists to disseminate the contents of the ECRAN project uniformly across countries. This section, addressed to journalists/peer-to-peer, has been conceived as a professional toolkit to introduce different aspects of knowledge and awareness about clinical trials (methodological aspects, how to get reliable information, how to report results, how to explain technical terms using a plain language, ...) and has been written by a group of expert professionals, able to communicate in a shared language. The organization of the media centre section in ECRAN website has taken as model the website dedicated to the media journalists. More specifically:

- A professional guide (e.g. "Guide to the critical interpretation of clinical trials") suited for journalists and showing all the tricks useful for the job.
- A list of FAQs for professionals.
- A quick presentation of ECRAN project.
- Several collections of valuable materials.
- The ECRAN newsletter.

Sibling Websites An interactive sibling web page under the title Testing Treatments. Testing Treatments is a book written for the public addressing many questions related to clinical research. A first edition was published by the British Library in 2006, and a second edition by Pinter and Martin in 2011. The book has been a great success, and has been translated into several languages. Preparation of the books was done as one element of the work of the James Lind Initiative, a programme of work coordinated by Iain Chalmers, an ECRAN partner, and funded by the English National Institute for Health Research. The English texts of both editions of the book are available for free download from Testing Treatments interactive (TTi) English – and translations are available in sibling TTi websites in other languages. All of the TTi websites also contain audio materials, videos, cartoons and other materials to enhance general knowledge of fair tests of treatments. It has to be highlighted that ECRAN website includes a direct link to each TTi sibling site available in a European language (English, Croatian, French, German, Italian, Norwegian, Polish, Portuguese, Spanish) and another link to TTi homepage (<http://www.testingtreatments.org/>) where users can search all the available translations.

Wikipedia The Wikipedia is far larger than any printed encyclopaedia, thus it is important reviewing pages related to the ECRAN keywords in terms of completeness, reliability, and readability of information reported. In the framework of the ECRAN project the revision of the existing Wikipedia pages in English, German, French, Italian, and Spanish has been performed. The revision of the pages language by language suggested that most key words are not covered by many languages and the availability of information on clinical trials is not uniform among the different languages considered. A new Wikipedia page on “independent clinical trials” covering the above topics has been setup in English and translated in Italian, French, Spanish, and German.

ECRAN Celebrating event Last May a Celebrating event in Luxembourg - where the ECRAN project and its tools and materials were officially presented – has been organized. This was a joint initiative – ECRAN, ECRIN-ERIC (European Clinical Research Infrastructures Network), ICTD (International Clinical Trials' Day) and CRP (Centre de recherché public) - to promote a transnational communication event on multinational clinical trials with the objective of facilitating better clinical research relevant to the needs of patients and highlight the important role of patients in clinical research. In order to facilitate the participation of citizens and patients associations a bursary was available to cover travel expenses. A total of 36 bursaries has been paid.

Finally, the last activity promoted by ECRAN partner is an open letter (petition) to all European Ministers of Education, European heads of schools, European teachers, and parents. The letter regards the introduction to clinical research as part of the school education for all European school pupils for three consecutive years around the ages of 14, 15, and 16 years, see at <http://www.ecranproject.eu/en/node/319>.

1.4 The potential impact and dissemination

The aim of the ECRAN project was to develop materials and tools on independent clinical trial reaching most of the European citizens with a core information in different European languages. Throughout the project there have been many opportunities to disseminate its contents and the materials. The interest on the issues considered by the project is very large at different levels: from the clinicians and the researchers directly involved in clinical research, citizens and to consumers and patients associations, to journalists or representatives of Ethics Committee.

The ECRAN activities have been promoted through:

- Congresses and meetings at local and international level, learning activities.
- Articles on magazines and newsletters.
- Website links, Blogs, twitters discussion lists.
- Letter to ad hoc mailing lists of consumers and patients associations, distribution of the ECRAN brochure.
- Organized networks such as European Clinical Research Infrastructures Network (ECRIN), Cochrane Consumers Network, PartecipaSalute and European AIDS Treatment Group (EATG).
- Network of clinicians such as ECRIN, Ethics Committees, clinical researchers groups has been invited to circulated the film, or to link of the film. The collaboration of some of the ECRAN partners or Advisory Board members has been requested as opinion leaders in networks of clinical researchers, or Ethics committees where they are involved.
- Journalists and media have been also involved in dissemination process.
- A Press release has been launched in January 2013.
- An Open letter (petition) to all European Ministers of Education, European heads of schools, European teachers, and parents <http://www.ecranproject.eu/en/node/319>.
- The Celebrating event in Luxembourg where ECRAN project was officially presented to scientific community, citizens and patients associations, and journalists.

Moreover a scientific article titled “An European multi-language initiative to make aware general population on independent clinical research: the ECRAN project” to convey information to the scientific community is ready to be submitted to a peer review journal.

This interest is witnessed by different articles published on magazines and newsletter, and by contributions on the different health information websites of associations of citizens and patients, by congress and meetings were ECRAN tools have been presented. At the level of clinicians and researchers ECRAN tools have been reported at conferences and congresses. Also in some large public events on science, such as Dusseldorf (research Night) or Genoa (Festival of Science) open

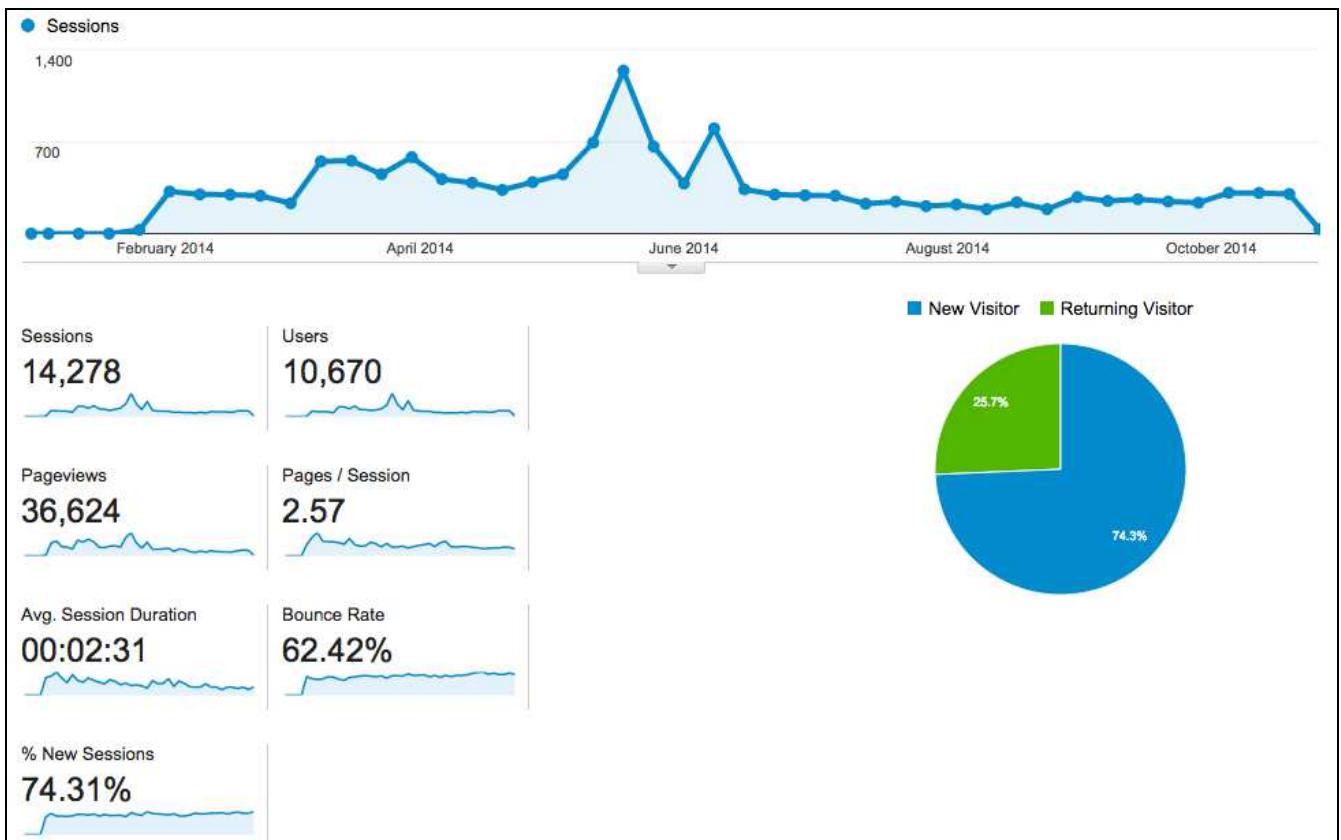
meeting, the ECRAN tools has been disseminated. The brochure on the project has also been circulating in different countries.

A summary of the dissemination activities is reported in the table below:

	TOTAL NUMBER	NUMBER OF ACTIVITIES BY TARGET		
		Scientific Community [^]	Lay people [^]	Several targets
Congresses, meetings, training courses	35	✓ (n=25)	✓ (n=13)	
Social Media	14			✓ (n=14)
Radio, talk show	4			✓
Websites	38 articles collected and reported in the Template A2			✓
Links	1120 links from 85 sites			✓
Articles published in the popular press	23			✓ (n=23)
Mailing lists, correspondences	7		✓ (n=4)	✓ (n=4)
Brochures	1.200 in English 2.000 in Italian 200 in German 200 in Spanish 200 in French 200 in Polish			✓

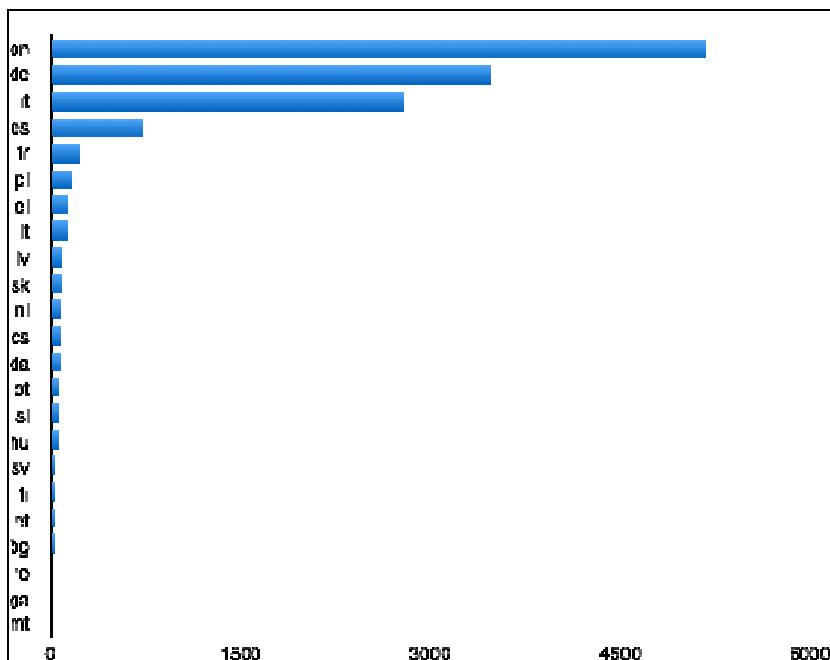
[^] Some activities had both scientific community and lay people as targets.

Regarding the ECRAN website, the last 8 months (January 2014-August 2014) of the project registered the audience reported in the figure below.



The top languages used were: English, Polish, Italian, German, France, Spanish, and the top 10 countries visiting the ECRAN website were: Italy, Poland, German, UK, France, United States, Spain, Belgium, Switzerland, and India.

Regarding the animated film, in the figure below is reported the number of views by languages for the period 2013 June to 2014 August: 13524 views on Vimeo. The film is available also through YouTube.



During the ECRAN project tools and materials have been developed and have been widely disseminated. However the real impact of this dissemination process would need an hoc research activity.

Considering the potential impact of the ECRAN project, together with the discussions that came out during the Celebrating event at the end of the project, some implications can be underline:

- Independent clinical research – if easily presented as by ECRAN tools – is an important key issue for lay people and their representatives, such as citizens' and patients' associations
- Clinical trial is a milestone of clinical research but still several aspects need to be discussed and shared among the different stakeholders
- The knowledge on clinical research among the general population needs to be increased
- European young people should be reach with ad hoc tools such as the ECRAN serious games to be involved in the health literacy process
- The translation and dubbing process of most of the ECRAN tools and materials developed supports the equity of access to the information regarding independent clinical research
- All stakeholders agreed on the importance to have a multidisciplinary discussion on clinical trials with the aims to increase the quality of clinical research, the dissemination of results, and the participation of patients
- Conflict of interest, transparency, and information are considered key issues to promote clinical research corresponding to the needs of patients and society and to obtain results useful to really change the clinical course of illness

During the work conducted within the project, it has become increasingly clear that results obtained with ECRAN could contribute to the development of high quality clinical research, in particular with joint initiatives with clinical groups, such as ECRIN-ERIC, the European Clinical Research Infrastructures Network.

Therefore, there were strong support among all participants of the ECRAN event to try to raise centralised funds for making an organisation like ECRAN viable for the future with its multi-stakeholder representation and a balanced view on evidence-based medicine and evidence-based clinical practise.

1.5 Dissemination

1.5.1 ECRAN logo



EUROPEAN COMMUNICATION ON
RESEARCH AWARENESS NEEDS

1.5.2 ECRAN website

The ECRAN Project aims to make understanding clinical trials - a relevant element of medical research - easy, and tells you all about taking part in them. [Read more](#)

Discover clinical trials >>

Randomisation, placebo, blinding... Medical research uses words that can be difficult when you first try to understand how new treatments are developed and tested. But it is simpler than you think!

Randomisation, placebo, blinding... Medical research uses words that can be difficult when you first try to understand how new treatments are developed and tested. But it is simpler than you think!

- Tutorial
- FAQs
- More contents

Dig out even more! >>

Many valuable resources already exist for learning about Clinical Trials. ECRAN has collected many of these all together in one place, letting you search quickly and easily for topics about which to discover more.

Search in inventory of resources

Search in inventory of resources

A game? Seriously... >>

ECRAN makes clinical trials easy

and... entertaining! Challenge yourself while playing ECRAN Lab and ECRAN Maze. Show-off how much you know about medical research and have fun learning even more.

Sail along with James Lind! >>

Back to 1747. The Scottish naval surgeon James Lind uncertain about how to treat scurvy, set up an experiment celebrated today as one of the earliest clinical trials. Enjoy the film and discover more about medical research.

Focus on

Cochrane and BMJ inquire Tamiflu and Relenza effectiveness >>
Research: increasing value, reducing waste >>
ECRAN's guide to clinical trials for professional >>
ECRAN FAQs >>
Clinical Trials deserve celebrations >>
COMET (Core Outcome Measures in Effectiveness Trials) Initiative >>
All trial campaign >>

Europe open letter education

It's time for school children to learn about clinical research

We will all benefit from more knowledge!

[Read the Open Letter and sign it!](#)

ECRAN & ICTD event

Communicate clinical research: two days for two great events >>

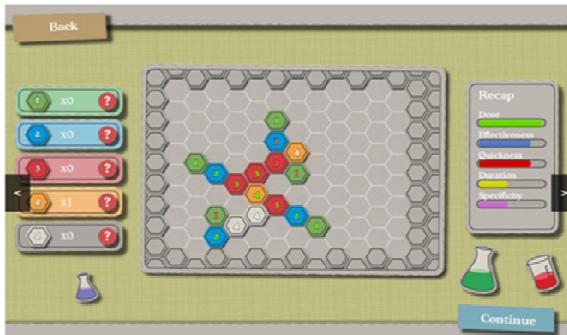
ECRAN & ICTD event

Communicate clinical research: two days for two great events >>

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1.5.3 ECRAN tools: serious games, tutorial, newsletter, sibling Testing Treatments Interaction



ECRAN Lab



What are clinical trials?

Controlled clinical trials conducted on large numbers of patients are essential for assessing the efficacy and safety of new treatments.

True False

Your choice is correct!

Introduction
Clinical trials
Why clinical trials?
Patients' interests
The Clinical Trial Process
Informed consent
Rights and protection
Trials Registers
Summary

Clinical research concerns everyone: the ECRAN project increases knowledge and awareness on independent clinical research

WHO WE ARE

In 2012 the European Commission funded the ECRAN (European Communication on Research Awareness Network) project, in order to improve the EU citizens' knowledge about medical research and, to support their participation in independent and multinational clinical trials.

FREE, EASY-TO-UNDERSTAND FILM ON CLINICAL TRIALS IN 23 LANGUAGES

One of the valuable ECRAN tools is characterized by an 5-minute **animated film on clinical trials**, dubbed in all 23 official European languages: <http://ecran-project.eu/ecran-tools/23-langs-james-lind>

It has been developed thanks to the collaboration among the ECRAN partners, the RAI-Superpark and the Studio Bozzetto & Co. Studio Bozzetto Studio Bozzetto, the James Lind in 1747. The animation film explains how his determined effort to treat scurvy finally turned out to be one of the earliest clinical trials in history and helped to establish the importance of randomised clinical experiments. The modular structure of this animation allows for display in full length or can be split into the following sections:

- A short history
- Ethics committees
- Randomization
- Double blinding
- Analyzing the data
- Outcomes important enough
- Outcomes important to patients
- Some pitfalls of trials

James Lind

2014 ECRAN | Project No. 105202 | Start date: 2012-09-01 | End date: 2014-08-31 | <http://www.ecranproject.eu>

Home Film Inventory of resources Serious game Testing Treatments About

Mediacenter

Home / Testing Treatments

Testing Treatments

What are fair tests of treatments? And why do we need them? Testing Treatments is a book written for the public addressing these and many more questions. A first edition was published by the British Library in 2006, and a second edition by Pinter and Martin in 2011. The book has been a great success, and has been translated into several languages. Preparation of the books was done as one element of the work of the James Lind Initiative, a programme of work coordinated by Iain Chalmers, an ECRAN partner, and funded by the English National Institute for Health Research.

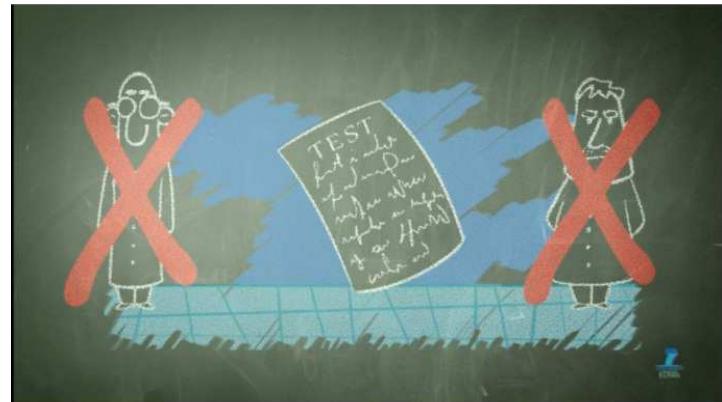
The English texts of both editions of the book are available for free download from Testing Treatments Interactive (TTI) <http://tti.bmjjournals.com> – and translations are available in sibling TTI websites in other languages. All of the TTI websites also contain audio materials, videos, cartoons and other materials to enhance general knowledge of fair tests of treatments.

Translation:

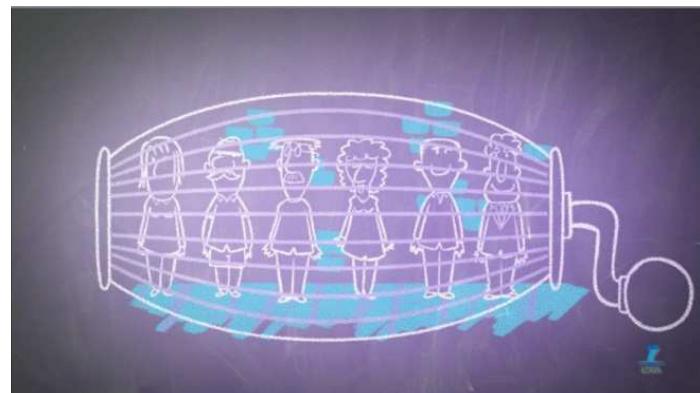
- English, <http://tti.bmjjournals.com>
- Croatian (funded by ECRAN)
- French (funded by ECRAN), <http://fr.testingtreatments.org>
- German (funded by ECRAN), <http://de.testingtreatments.org>
- Italian (funded by ECRAN), <http://it.testingtreatments.org>
- Norwegian (funded by ECRAN), <http://no.testingtreatments.org>
- Polish (funded by ECRAN), <http://pl.testingtreatments.org>
- Portuguese, <http://pt.testingtreatments.org>
- Spanish, <http://es.testingtreatments.org>

1.5.4 ECRAN animated film: Clinical research matters to you: do you want to know more?

The Ethics Committees



The randomization process



The masking process



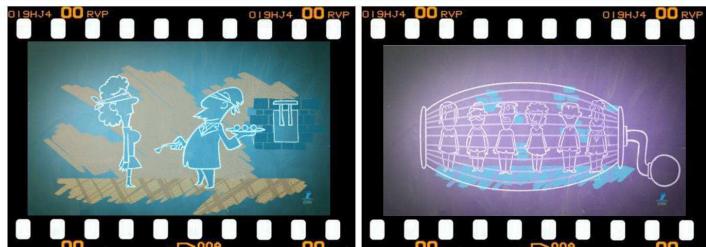
1.5.5 ECRAN poster

CLINICAL RESEARCH MATTERS TO YOU: DO YOU WANT TO KNOW MORE?

*The ECRAN project to increase knowledge and awareness
on independent clinical research*

The European Commission funded in 2012 the ECRAN project - European Communication on Research Awareness Needs - to improve the EU citizens' knowledge about medical research, and to support their participation in independent and multinational clinical trials. The ECRAN project aims to inform citizens and patients - principal target of the project - but also healthcare professionals, researchers, and journalists about the importance of public knowledge about clinical trials, the need for independent clinical trials driven by healthcare issues, the need for transparency and optimal use of data, and the need for multinational cooperation, taking advantage of Europe population size and diversity. The multidisciplinary consortium of the ECRAN project includes methodologists directly involved in clinical trials, researchers involved in partnership collaboration with citizens and patients, representatives of citizens and patients, and experts of science communication: IRCCS-IRFMN Italy, INSERM France, KKS-Network Germany, Oxford Un Hospitals NHS Trust UK, CTU Denmark, UKL-FR Germany, Zadig Italy, CCNET UK, and EATG Belgium.

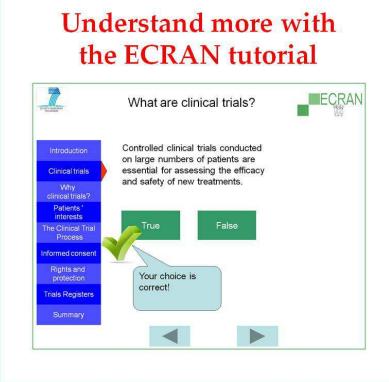
**Watch the ECRAN film
It's available in 25 languages**



**Visit our website
<http://ecranproject.eu>
It's available in 6 languages**



**Understand more with
the ECRAN tutorial**



**Learn and play with
ECRAN Lab and ECRAN Maze
on your tablet, it's entertaining!
Download the games on your tablet**



All the materials and tools are developed under creative common license and are freely available at the website of the project <http://www.ecranproject.eu>



1.5.6 ECRAN brochure (in English)



Visit our website
<http://ecranproject.eu>

Watch the film
It's available in 23 languages

Play ECRAN Lab and ECRAN Maze
on your tablet, it's entertaining!
Use the QR-code to download the games
on your tablet



Android Apple Windows

The ECRAN project (European Communication on Research Awareness Needs) is part of the EU's continuing effort to improve the health of its citizens. ECRAN has been designed to support the European Commission's strategy of funding independent multinational clinical trials to:

- optimize healthcare and clinical research strategies
- promote cost-effective treatments, reducing the economic burden of diseases
- take advantage of the EU population's size, diversity and medical expertise

ECRAN focuses on:

- explaining the basic principles of clinical trials in plain terms
- fostering patients' active participation in clinical trials
- involving patients and citizens associations in designing trials
- collaborating with the European medical and research community

ECRAN offers plenty of resources, FAQs, tutorials, videos, serious games, an inventory and even a film... ECRAN makes clinical trials easy to understand... and tells you all about taking part in medical research... in 23 EU languages.



Discover clinical trials
Randomisation, placebo, blinding... medical research uses words that can be difficult when you first try to understand how new treatments are developed and tested. But it is simpler than you think!

A user-friendly website in 23 languages, ECRAN – <http://ecranproject.eu> – has been developed to inform all European citizens about clinical trials and boasts among his partners the authors of the successful book *Testing Treatments*, now translated in several languages thanks to support from ECRAN and others. ECRAN also actively participates in International Clinical Trials' Day.

So, what are you waiting for?

Visit our pages, subscribe to our newsletter, answer the online survey and consult the ECRAN inventory of resources if you want to learn even more.

You are most welcome!



Participate in ECRAN social networks
ECRAN project wants to hear your voice. Follow us on:

- <https://www.facebook.com/ecran.project>
- <https://twitter.com/ecranproject>



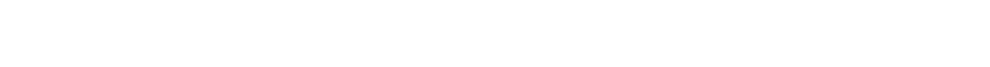
Be ECRAN-social!
We look forward to receiving your comments, proposals and suggestions



Sail along with James Lind
A 23 languages film on clinical trials by ECRAN



Back in 1747, James Lind had never heard about clinical trials! Lind was a Scottish naval surgeon, and he found himself on a Royal Navy ship with many sailors sick with scurvy. His ideas helped to revolutionise our understanding of how to find out which treatment might work best. His work not only saved lives on his ship, but laid the foundation for modern clinical trials – randomised controlled trials – as we know them today.



Two games? Seriously...

ECRAN Lab Enter a virtual experimental laboratory and play through the clinical trial phases! Make a new drug, check if it's safe and effective, fight the bad cells within the human body and protect the good ones with the help of your tutor, an old and very wise scientist!

ECRAN Maze Don't get lost in the maze! Answer all the questions along the path and do it quickly if you want to score high! Just as researchers need to address uncertainty about treatment effects, your task is to get through the labyrinth finding the right solution each time.



1.6 Consortium and acknowledgments

ECRAN is co-funded by the 7th Framework Programme of the EU and coordinated by the IRCCS-Mario Negri Institute (Paola Mosconi, Silvio Garattini) with the participation of the following European partners:

- Institute national de la santé et de la recherche médicale France
Jacques Demotes-Mainard
- KKS-Network of the Coordinating Centres for Clinical Trials, University Hospital of Cologne Germany
Stephanie Wolf
- Oxford University Hospitals NHS Trust United Kingdom
Amanda Burls, Sir Iain Chalmers
- Rigshospitalet Copenhagen University Hospital Copenhagen Trial Unit RegH Denmark
Christian Gluud
- University Medical Center Freiburg Universitätsklinikum Germany
Gerd Antes
- Zadig, editorial and publishing company Italy
Roberto Satolli
- Cochrane Consumer Network United Kingdom
Gill Gytte
- European AIDS Treatment Group Belgium
Brian West.

People working in the different WPs of the project Alicia Szofer-Araya (Institute national de la santé et de la recherche médicale France), Giorgio Barbareschi (European AIDS Treatment Group Belgium), Christa Bast (University Medical Center Freiburg Universitätsklinikum Germany), Koen Block (European AIDS Treatment Group Belgium), Insa Bruns (KKS-Network of the Coordinating Centres for Clinical Trials, University Hospital of Cologne Germany), Giulia Candiani (Zadig, editorial and publishing company Italy), Sergio Cima (Zadig, editorial and publishing company Italy), Cinzia Colombo (IRCCS- Mario Negri Institute Italy), Nikos Dedes (European AIDS Treatment Group Belgium), Berit Grevstad, Paolo Griselli (Zadig, editorial and publishing company Italy), Christine Kubiak (Institute national de la santé et de la recherche médicale France), Marco Milano (Zadig, editorial and publishing company Italy), Catherine McIlwain (Cochrane Consumer Network United Kingdom), Matt Penfold (Oxford University Hospitals NHS Trust United Kingdom), Niccolò Pieri (IRCCS- Mario Negri Institute Italy), Nils Post (KKS-Network of the Coordinating Centres for Clinical Trials, University Hospital of Cologne Germany), Anna Roberto (IRCCS- Mario Negri Institute Italy), Maria Rosa Valetto (Zadig, editorial and publishing company Italy), Studio Bozzetto and Co, Rai SuperQuark.

2. Use and dissemination of foreground

TEMPLATE A2: LIST OF DISSEMINATION ACTIVITIES

NO.	Type of activities ²	Main Leader ^	Title	Date/Period	Place	Type of audience ³	Size of audience ^^	Countries addressed
1	Congress	3	ECRIN European Clinical Research Infrastructures Network	April 2013	Warsaw	Scientific Community	About 100	International
2	Congress	1	EUPATI European Patients' Academy on Therapeutic Innovation	April 2013	Roma	Lay people	About 100	International
3	Summer school	3	EURORDIS Rare diseases Europe Summer school for patient advocates in clinical trials and drug development	June 2013	Barcelona	Lay people		International
4	Public Event	9	Patient-Information-Day about Cancer, Universitätsklinikum	September 2013	Dusseldorf	Lay People		National
5	Workshop	1	ECRIN Network EUCO	September 2013	Paris	Scientific Community		International
6	Public Event	9	Researcher Night, Museum Kunstpalast	September 2013	Dusseldorf	Lay People		National
7	Congress	1	21st Cochrane Colloquium, Better knowledge for better health	September 2013	Quebec	Scientific Community		International
8	Public Event	1	Public meeting on Ovarian Cancer	October 2013	Milano	Lay People	80	National
9	Summer school	3	ECRIN Summer School	October 2013	Izmir	Scientific Community		International

² A drop down list allows choosing the dissemination activity: publications, conferences, workshops, web, press releases, flyers, articles published in the popular press, videos, media briefings, presentations, exhibitions, thesis, interviews, films, TV clips, posters, Other.

³ A drop down list allows choosing the type of public: Scientific Community (higher education, Research), Industry, Civil Society, Policy makers, Medias, Other ('multiple choices' is possible).

10	Conference	1	Ten years activities of PartecipaSalute	November 2013	Milano	Scientific Community and Lay people	80	National
11	Workshop	3	Workshop Multinational Clinical Trials with ECRIN4 and ECRIN2 Partners: Structures, Procedures, Challenges German National ECRIN-Office in cooperation with the Head Office of the KKS-Network	November 2013	Frankfurt	Scientific Community		International
12	Conference	4	EBHC International Joint Conference. Evidence, Governance, Performance	October 2013	Taormina	Scientific Community		International
13	Training course	1	Training course for Citizens and Patients Associations, PartecipaSalute & Regione Toscana	October 2013	Montecatini Terme	Lay People	30	National
14	Public Event	2	Festival della scienza http://www.festivalscienza.it/si-te/home/programma/giorno-per-giorno/1-novembre/malati-rari-e-ricercatori-una-collaborazi.html	November 2013	Genova	Lay People	50	National
15	Conference	1	ACLI Associazioni cristiane lavoratori italiani: L'uso corretto dei farmaci	Novembre 2013	Treviso	Scientific Community	40	National
16	Workshop	9	Workshop CECAD Cologne Risk-Based-Monitor-Strategies	December 2013	Cologne	Scientific Community		International
17	Meeting	1	Meeting of members of Associazione A Liberati-	December 2013	Napoli	Scientific Community	40	National

			Network Italiano Cochrane					
18	Congress	1	OPEN-AL-NIC: dalla condivisione dei risultati ad una ricerca trasparente per il bene comune	December 2013	Napoli	Scientific Community	140	National
19	Master	1	Master 'Ricerca Clinica'- 'Clinical Research' 2013/2014, Università di Milano	2013/2014	Milano	Scientific Community	30	National
20	Course	4	Undergraduate and postgraduate health degrees on the Virtual Learning Environment. City University London	2013/2014	United Kingdom	Scientific Community		National
21	Course	9	KKS Cologne decided to show the ECRAN film at the beginning of each course	2013/2014	Germany	Scientific Community		National
22	Course	1	Università di Milano, Dipartimento di Scienze Biomediche per la Salute, corsi di Laurea 2014	2014	Milano	Scientific Community		National
23	Meeting	3	Official inauguration of ECRIN-ERIC	January 2014	Brussels	Scientific Community	100	International
24	Meeting	8	ECAB-EATG European AIDS Treatment Group meeting	January 2014	Brussels	Lay people	30	International
25	Meeting	4	City University London ,Inaugural lecture on Public and Patient Involvement in Health Research	February 2014	London	Scientific Community		National
26	Public Event	1	Inaugurazione A.A. 2013-2014 Università Milano - Laurea Honoris Causa Prof. Garattini	February 2014	Milano	Scientific Community	120	National
27	Congress	1	3° Convegno Nazionale sulla Ricerca Indipendente in Italia, Ministero della Salute	March 2014	Roma	Scientific Community		National

28	Conference	1	Università degli Studi di Milano "La Responsabilità dell'Accademia nello Sviluppo e nell'impiego dei Farmaci"	April 2014	Milano	Scientific Community		National
29	Conference	1	COMECA sulla Ricerca Clinica "L'Etica della Sperimentazione Clinica"	April 2014	Mendrisio	Scientific Community		National
30	Congress	9	Quality by Design - Key factors for the success of a clinical trial and safeguard for patient safety and data quality	May 2014	Cologne	Scientific Community		National
31	Meeting	6	International Clinical Trial's Day	May 2014	Luxembourg	Scientific Community and Lay People	150	International
32	Conference	1	Associazione Cultura e Sviluppo	May 2014	Alessandria	Lay people		National
33	Conference	1	"Bioetica Clinica e Metodologia della Ricerca Scientifica" The Role of Ethics in the Relation with Pharma and Regulatory Authorities	June 2014	Firenze	Scientific Community		National
34	Training course	1	Incontro Scuola Superiore di Magistratura. Aspetti di Metodo Scientifico a partire dal caso Stamina. La Sperimentazione Clinica	June 2014	Roma	Lay people		National
35	Conference	3	iCAN: Pan-European Conference on Community Empowerment and Sustainable Response to HIV/AIDS	October 2014	Warsaw	Scientific Community and Lay people		International
1	Social Media	4	Caspuk@caspuk			Several targets	338 followers	International

2	Social Media	1	GIORDANO @giordanopg			Several targets	597 followers	National
3	Social Media	4	Trish Groves @trished			Several targets	3733 followers	International
4	YouTube	1	http://www.youtube.com/watch?v=PrQDYNk4CU0			Several targets		International
5	Facebook	1	Italian Cochrane Network page			Several targets		National
6	Social Media	7	Blog of GWUP e.V. (association of sceptics) http://blog.gwup.net/2013/08/24/wo-ist-der-beweis-verlassliche-informationen-gegen-haltlose-versprechen/			Several targets		National
7	Social media	7	http://scienceblogs.de/gesundheits-check/2013/08/21/wo-ist-der-beweis-jetzt-online-abrufbar/			Several targets		National
8	Blogs	7	Blog Wissensküche with reference to website TTi http://wissenskueche.de/2013/05/fur-evidenz-statt-eminenz-20-jahre-cochrane/			Several targets		National
9	Newsblog	7	Newsblog of the University of Mannheim http://www.umm.uni-heidelberg.de/apps/bibl/mwbne ws/?p=5348			Several targets		National
10	YouTube	1	Spanish YouTube http://www.youtube.com/watch?v=PrQDYNk4CU0			Several targets		National
11	Facebook	1	Spanish facebook http://www.facebook.com/Pyd esalud			Several targets		National

12	Social media	5	CC-Net social media: targeted Tweets to 43 organizations with larger numbers of followers			Several targets		International
13	YouTube	4/5	https://www.youtube.com/watch?v=mlLEwSxHeXU&feature=em-upload_owner			Several targets		International
14	YouTube	4/5	https://www.youtube.com/watch?v=Va7e0GBdpeM&feature=em-upload_owner			Several targets		International
1	Talk show	7	Menschen bei Maischberger, 11 Sept. 2013 (TV).			Several targets		National
2	Radio	7	The radio station is Bayern 2, in Munich, Bavaria. On the web page http://www.br.de/radio/bayern2/sendungen/notizbuch/medikamenten-studien-russland-100.html			Several targets		National
3	Radio	7	Recommended as background reading in science magazine on channel 1 (ARD) in Science Magazine Quarks&Co, 4 June 2013 http://www.wdr.de/tv/quarks/sendungsbeitraege/2013/0604/lestipps_pfusch.jsp			Several targets		National
4	Radio	1	RAI-Radio3Scienza, 14 May 2014 http://www.radio3.rai.it/dl/radio3/programmi/puntata/ContentItem-a9540107-f59b-40ab-97ed-181d623957eb.html			Several targets		National

1	Website		http://www.psoriasis-netz.de/lesen-a-sehen/unsere-buchtipps/wo-ist-der-beweis.html			Several targets		International
2	Website	7	http://www.sindbad-mds.de/infomed/sindbad.nsf/02568A2003D5BAE/2130ACE59F2C8B0EC1257BB300435689?OpenDocument			Several targets		International
3	Website	7	German Cochrane Centre website: http://www.cochrane.de/de/weibliographie-studien			Several targets		National
4	Website	7	http://www.medien-doktor.de/medizin/sprechstunde/lesetipp-testing-treatmentswo-ist-der-beweis/			Several targets		National
5	Website	1	http://www.patientsacademy.eu/index.php/en/news/320-eupati-2014-workshop			Several targets		International
6	Website	1	http://www.partecipasalute.it/cms_2			Several targets		National
7	Website	2	http://www.scienzainrete.it/contenuto/news/ecran-project-cartone-descrivere-trials-clinici/settembre-2013			Several targets		National
8	Website	7	German Cochrane Centre website: http://www.cochrane.de/de/weibliographie-studien			Several targets		National
9	Website	7	Website of German Network for EBM: page about			Several targets		National

			understand clinical research with link to film http://www.ebm-netzwerk.de/aktuelles/news2013-09-05					
10	Website	7	http://de.testingtreatments.org/ with the German title “Wo ist der Beweis?” Film promoted on web platform for Rehabilitation Medicine			Several targets		National
11	Website	7	http://www.ihre-vorsorge.de/magazin/nachrichten/gesundheit/news-single/article/lebenswichtige-klinische-studien.html			Several targets		National
12	Website	3	Several ECRIN correspondents are uploading the film on their respective national Website http://www.sueddeutsche.de/gesundheit/evidenzbasierte-medizin-wo-ist-der-beweis-1.1785151			Several targets		International
13	Website	2	Scienza in rete http://www.scienzainrete.it/contenuto/news/ricerca-clinica-riguarda-anche-te-vuoi-saperne-di-piu/gennaio-2014			Several targets		National
14	Website	1	Vita http://www.vita.it/welfare/salute/divulgare-la-conoscenza-ci-pensa-il-progetto-ecran.html			Several targets		National
15	Website	1	Dors Piemonte Regione http://www.dors.it/pag.php?idc=4461			Several targets		National

16	Website	1	Famiglie SMA http://www.famigliesma.org/index.php?option=com_content&view=article&id=475&Itemid=653#.UtP5H4H4Kj4			Several targets		National
17	Website	1	La lampada di Aladino http://www.lampada-aladino.it/			Several targets		National
18	Website	1	Sindrome di Crisponi http://www.sindromedicrisponi.it/			Several targets		National
19	Website	1	COMET Core Outcome Measures in Effectiveness Trials http://www.comet-initiative.org/assets/downloads/COMETnewsletter.April2014.pdf			Several targets		International
20	Website	1	Beta WEB http://www.medicaltradefair.com/ToM_01_14_StudyApproach			Several targets		International
21	Website	9	http://www.kks-netzwerk.de/ecran.html ECRAN Project			Several targets		National
22	Website	1	http://crasecrets.com/il-video-della-ricerca-clinica/			Several targets		National
23	Website	4	www.ithinkwell.org			Several targets		International
24	Website	2	http://www.scienzainrete.it/contenuto/news/ecran-project-cartone-descrivere-trials-clinici-settembre-2013			Several targets		National
25	Website	1	http://www.oilproject.org/lezione/vaccini-ricerca-scientifica-			Several targets		National

			studi-clinici-10420.html					
26	Website	4	http://www.students4bestevidence.net/ecranks-video-about-clinical-research-how-does-it-stack-up/			Several targets		International
27	Website	1	http://assr.regione.emilia-romagna.it/it/notizie/home/dove-sono-le-prove			Several targets		National
28	Website	7	http://www.cochrane.de/de/news/ecran-projekt-newsletter-und-petition			Several targets		National
29	Website	1	http://www.fondazionemattioli.it/index.php?option=com_content&view=article&id=55:etempo-che-i-ragazzi-sappiano-che-cosa-e-la-ricerca-clinica-firma-l-appello-ecran&catid=8:news&Itemid=169			Several targets		National
30	Website	1	http://www.usl1.toscana.it/sezioni.php?seid=1012			Several targets		National
31	Website	9	http://www.pan-austria.org/site/index.php?c=ansicht2&id=26			Several targets		National
32	Website	1	http://www.europadonna.at/index.php/24-newsflash/186-klinische-studien			Several targets		National
33	Website	1	http://www.pydesalud.com/			Several targets		National
34	Website	1	www.gimbe.org/elenconeNews/552/it?categoria=5&anno=2014			Several targets		National
35	Website	1	http://www.ilgalileo.eu/n26/briichi.html			Several targets		National
36	Website	2	http://bestwindows8apps.net/ecranlab			Several targets		National

37	Website	2	http://bestwindows8apps.net/e_cranmaze			Several targets		National
38	Website	1	http://www.ails.it/portale/la-ricerca-clinica-riguarda-anche-te-vuoi-saperne-di-più/			Several targets		National
1	Mailing list	8	French HIV and Hepatitis NGOs that are on the mailing list of TRT-5 (the French CAB) and to the Viral Hepatitis Coalition (CHV)			Lay people		National
2	Mailing list	7	Email list „ebm-l“: 1418 members, list of German Network for EBHC (in German language)			Scientific community		National
3	Mailing list	7	Email list „cochrane-l“: 1164 members, list of German Cochrane Network (in German language, run by German Cochrane Centre)			Scientific community		National
4	Mailing list	7	Email list only in German language (maintained by Gerd Antes) for science journalists in Germany, Switzerland and Austria: 265 journalists (employed or freelancers, editorial offices)			Lay people		National
5	Mailing list	1	Email list: PartecipaSalute and Laboratory for medical research and consumer involvement, Mario Negri Institute, e-mail to 1230 address			Lay people and Scientific community	2000	National
6	Mailing list	7/9	The letter with a link to the			Lay people		National

			German petition text on the ECRAN website was sent to all 14 German ministries of education. It contains a brief description of the project, the link to the German petition and the request to distribute it among school principals, teachers and parents.					
7	Correspondence	2	Science and Innovation Officer British Consulate General, Alessandra Ferraris reply to Catherine Luckin, Head of International, The Academy of Medical Sciences (http://www.acmedsci.ac.uk).			Scientific community		National
1	Brochures	1	ECRAN Brochure distribution: 1200 in English, 2000 in Italian, 200 in German, 200 in Spanish, 200 in Polish, and 200 in French.			Lay people		International
1	Article published in the popular press	1	Trial without tribulation. International Innovation. Issue 152, 2014			Scientific community, Lay people		International
2	Article published in the popular press	2	L'Espresso 23 May 2013 (magazine), Guai a chi imbroglio			Lay people		National
3	Article published in the popular press	7	Spiegel online 1 Aug 2013 (magazine) http://www.spiegel.de/gesundheit/diagnose/frueherkennung-			Lay people		National

			von-krebs-us-aerzte-fordern-weniger-krebsdiagnosen-a-913830.html				
4	Article published in the popular press	7	Spiegel online 9 Aug.2013 http://www.spiegel.de/wissenschaft/medizin/kakao-us-studie-weist-irrefuehrendes-ergebnis-aus-a-915332.html			Lay people	National
5	Article published in the popular press	7	Frankfurter Allgemeine Zeitung (daily newspaper, FAZ) 1 Sept 2013 http://www.seiten.faz-archiv.de/fas/20130901/sd1201309013976413.html			Lay people	National
6	Article published in the popular press	1	Corriere della Sera http://www.corriere.it/salute/13_dicembre_10/come-funziona-studio-clinico-spiega-cartone-animato-6bc24ab8-61a6-11e3-9835-2b4fbcb116d9.shtml			Lay people	National
7	Article published in the popular press	1	AUSL-Milano e-mail Newsletter (1100 General Practitioners)			Lay people	National
8	Article published in the popular press	1	Health desk http://www.healthdesk.it/daily/sai_come_funziona_uno_studio_clinico/1389699020			Lay people	National
9	Article published in the popular press	1	Blog Scire http://www.scire-ausl.bo.it/dblog/articolo.asp?articolo=180			Lay people	National
10	Article published in the popular press	1	Focus http://www.focus.it/scienza/salute/come-si-sperimenta-un-			Lay people	National

			<u>farmaco_C12.aspx</u>				
11	Article published in the popular press	1	Clic Medicina La ricerca clinica riguarda anche te: vuoi saperne di più? http://www.clicmedicina.it/pagine-n-56/ricerca-clinica-08702.htm			Lay people	National
12	Article published in the popular press	1	AIS-Sanità Ricerca clinica, Istituto Mario Negri: UE finanzia progetto per promuoverla http://www.ais-sanita.it/ricerca-sviluppo-e-tecnologia/15687-ricerca-clinica-ist-m-negri-ue-finanzia-progetto-per-farla-conoscere-a-cittadini.html			Lay people	National
13	Article published in the popular press	1	Asca IRCCS Istituto Mario Negri, UE finanzia progetto su ricerca clinica http://www.asca.it/newsregioni/_Sanita_Irccts_Mario_Negri_Ue_finanzia_progetto_su_ricerca_clinica-1353904-.html			Lay people	National
14	Article published in the popular press	1	Pharmastar La ricerca clinica riguarda anche te: un video per saperne di più http://www.pharmastar.it/index.html?cat=7&id=13475			Lay people	National
15	Article published in the popular press	1	Quotidiano Sanità. Mario Negri: Al via progetto per aumentarne la conoscenza e a partecipazione a studi			Lay people	National

			indipendenti http://www.quotidianosanita.it/ scienza-e- farmaci/articolo.php?articolo_id=19091				
16	Article published in the popular press	1	L'eco Di Bergamo Cartoon di bozzetto per spiegare la ricerca http://www.ecodibergamo.it/ stories/La%20Salute/cartoon-di- bozzetto-per-spiegare-la- ricerca_1041029_11/			Lay people	National
17	Article published in the popular press	1	Farmacistaonline Mario Negri. Al via progetto per aumentarne la conoscenza e a partecipazione a studi Indipendenti http://www.ilfarmacistaonline. it/scienza-e- farmaci/articolo.php?articolo_id=19091			Lay people	National
18	Article published in the popular press	1	ANSA canale Salute e Benessere progetto negri divulgà sperimentazione ai cittadini http://staging.ansa.it/saluteebe/ nessere/notizie/pro/regioni/lom- bardia/2014/01/13/Film- animazione-spiegare-ricerca- clinica-progetto- Ue_9888091.html#content- corpo			Lay people	National
19	Article published in	1	Sardiniapost Sanità: IRCCS Mario Negri, UE finanzia			Lay people	National

	the popular press		progetto su ricerca clinica				
20	Article published in the popular press	1	L'Unione europea e la ricerca clinica. Newsletter Associazione Alessandro Liberati-Network Italiano Cochrane, maggio 2014 http://associali.it/newsletter/pdf/y9_Maggio-2014_Una%20corretta-ed-efficace-assunzione-dei-farmaci.pdf			Lay people	National
21	Article published in the popular press	9	Newsletter Circular, newsletter des KKS-Netzwerks Nr. 22 http://www.kks-netzwerk.de/uploads/download/CIRCULAR_22_KKS_N_Dez_2013.pdf			Lay people	National
22	Article published in the popular press	1	Healthdesk http://www.healthdesk.it/ricerca/fate_studiare_la_ricerca_clinica_a_scuola/1406037561			Lay people	National
23	Article published in the popular press	1	Morfologie Gli studi clinici cosa sono e come sapere di più seconda parte http://pubblicazioni.apmar.it/SB3DBook/Morfologie14_2014/3dbook.swf			Lay people	National

^ Main leading contributor for the ECRAN Partners: 1=IRCCS-Istituto Mario Negri; 2= Zadig Editorial and publishing company; 3= Institute National de la Santè et de la Recherche Médicale; 4= Oxford University Hospitals; 5= Cochrane Consumer Network (via Cochrane Collaboration); 6= Rigshospitalet, Copenhagen University Hospital Copenhagen, Trial Unit; 7= University Medical Center Freiburg (Universitäsklinikum Freiburg); 8= European AIDS Treatment Group; 9= German Network of the Coordinating Centres for Clinical Trials U Koeln. ^^ Some information is missing because it is impossible to obtain the data

3. Report on societal implications

Replies to the following questions will assist the Commission to obtain statistics and indicators on societal and socio-economic issues addressed by projects. The questions are arranged in a number of key themes. As well as producing certain statistics, the replies will also help identify those projects that have shown a real engagement with wider societal issues, and thereby identify interesting approaches to these issues and best practices. The replies for individual projects will not be made public.

A General Information (*completed automatically when Grant Agreement number is entered.*)

Grant Agreement Number:

305125

Title of Project:

European Communication on Research Awareness
Needs - ECRAN

Name and Title of Coordinator:

Paola Mosconi, Biol Sci D

B Ethics

1. Did your project undergo an Ethics Review (and/or Screening)?

- If Yes: have you described the progress of compliance with the relevant Ethics Review/Screening Requirements in the frame of the periodic/final project reports?

No

Special Reminder: the progress of compliance with the Ethics Review/Screening Requirements should be described in the Period/Final Project Reports under the Section 3.2.2 'Work Progress and Achievements'

2. Please indicate whether your project involved any of the following issues (tick box):

YES

RESEARCH ON HUMANS

- Did the project involve children?
- Did the project involve patients?
- Did the project involve persons not able to give consent?
- Did the project involve adult healthy volunteers?
- Did the project involve Human genetic material?
- Did the project involve Human biological samples?
- Did the project involve Human data collection?

No

No

No

No

No

No

No

RESEARCH ON HUMAN EMBRYO/FOETUS

- Did the project involve Human Embryos?
- Did the project involve Human Foetal Tissue / Cells?
- Did the project involve Human Embryonic Stem Cells (hESCs)?
- Did the project on human Embryonic Stem Cells involve cells in culture?
- Did the project on human Embryonic Stem Cells involve the derivation of cells from Embryos?

No

No

No

No

No

PRIVACY

- Did the project involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?

No

• Did the project involve tracking the location or observation of people?	No	
RESEARCH ON ANIMALS		
• Did the project involve research on animals?	No	
• Were those animals transgenic small laboratory animals?	No	
• Were those animals transgenic farm animals?	No	
• Were those animals cloned farm animals?	No	
• Were those animals non-human primates?	No	
RESEARCH INVOLVING DEVELOPING COUNTRIES		
• Did the project involve the use of local resources (genetic, animal, plant etc)?	No	
• Was the project of benefit to local community (capacity building, access to healthcare, education etc)?	No	
DUAL USE		
• Research having direct military use	No	
• Research having the potential for terrorist abuse	No	
C Workforce Statistics		
3. Workforce statistics for the project: Please indicate in the table below the number of people who worked on the project (on a headcount basis).		
Type of Position	Number of Women	Number of Men
Scientific Coordinator	1	0
Work package leaders	3	4
Experienced researchers (i.e. PhD holders)	5	2
PhD Students	0	0
Other	6	6
4. How many additional researchers (in companies and universities) were recruited specifically for this project?		
Of which, indicate the number of men:		

D Gender Aspects

5. Did you carry out specific Gender Equality Actions under the project?	<input checked="" type="radio"/> X	Yes
		No

6. Which of the following actions did you carry out and how effective were they?

		Not at all effective	Very effective
<input type="checkbox"/> Design and implement an equal opportunity policy		<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Set targets to achieve a gender balance in the workforce		<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Organise conferences and workshops on gender		<input type="radio"/>	<input type="radio"/>
<input type="checkbox"/> Actions to improve work-life balance		<input type="radio"/>	<input type="radio"/>
<input type="radio"/> Other:			

7. Was there a gender dimension associated with the research content – i.e. wherever people were the focus of the research as, for example, consumers, users, patients or in trials, was the issue of gender considered and addressed?

Yes- please specify

X No

E Synergies with Science Education

8. Did your project involve working with students and/or school pupils (e.g. open days, participation in science festivals and events, prizes/competitions or joint projects)?

X Yes- please specify

Tools and materials, in particular ECRAN video, have been disseminate in public event such Night of Researchers, or Science Festival. ECRAN serious games have been tested in a high school.

O No

9. Did the project generate any science education material (e.g. kits, websites, explanatory booklets, DVDs)?

X Yes- please specify

ECRAN project generated several science education materials, such as animated film, tutorials, serious games, websites.

O No

F Interdisciplinarity

10. Which disciplines (see list below) are involved in your project?

3 Main discipline⁵:

5.3 Associated discipline⁵:

Associated discipline⁵:

G Engaging with Civil society and policy makers

11a Did your project engage with societal actors beyond the research community? (if 'No', go to Question 14)	<input checked="" type="radio"/> X	Yes
	<input type="radio"/> O	No

11b If yes, did you engage with citizens (citizens' panels / juries) or organised civil society (NGOs, patients' groups etc.)?

O No

O Yes- in determining what research should be performed

⁵ Insert number from list below (Frascati Manual).

Yes - in implementing the research
 Yes, in communicating /disseminating / using the results of the project

11c In doing so, did your project involve actors whose role is mainly to organise the dialogue with citizens and organised civil society (e.g. professional mediator; communication company, science museums)?		<input checked="" type="checkbox"/>	Yes No
12. Did you engage with government / public bodies or policy makers (including international organisations)			
<p><input checked="" type="checkbox"/> No <input type="radio"/> Yes- in framing the research agenda <input type="radio"/> Yes - in implementing the research agenda <input type="radio"/> Yes, in communicating /disseminating / using the results of the project</p>			
13a Will the project generate outputs (expertise or scientific advice) which could be used by policy makers?			
<p><input checked="" type="checkbox"/> Yes – as a primary objective (please indicate areas below- multiple answers possible) <input type="radio"/> Yes – as a secondary objective (please indicate areas below - multiple answer possible) <input type="radio"/> No</p>			
13b If Yes, in which fields? Education, Training, Youth, Public Health, Consumers			
Agriculture Audiovisual and Media Budget Competition Consumers Culture Customs Development Economic and Monetary Affairs Education, Training, Youth Employment and Social Affairs	Energy Enlargement Enterprise Environment External Relations External Trade Fisheries and Maritime Affairs Food Safety Foreign and Security Policy Fraud Humanitarian aid	Human rights Information Society Institutional affairs Internal Market Justice, freedom and security Public Health Regional Policy Research and Innovation Space Taxation Transport	

13c If Yes, at which level?

- Local / regional levels
- National level
- European level
- International level

H Use and dissemination

14. How many Articles were published/accepted for publication in peer-reviewed journals?	0	
To how many of these is open access⁶ provided?		
How many of these are published in open access journals?		
How many of these are published in open repositories?		
To how many of these is open access not provided?		
<p>Please check all applicable reasons for not providing open access:</p> <ul style="list-style-type: none"> <input type="checkbox"/> publisher's licensing agreement would not permit publishing in a repository <input type="checkbox"/> no suitable repository available <input type="checkbox"/> no suitable open access journal available <input type="checkbox"/> no funds available to publish in an open access journal <input type="checkbox"/> lack of time and resources <input type="checkbox"/> lack of information on open access <input type="checkbox"/> other⁷: 		
15. How many new patent applications ('priority filings') have been made? <i>("Technologically unique": multiple applications for the same invention in different jurisdictions should be counted as just one application of grant).</i>	0	
16. Indicate how many of the following Intellectual Property Rights were applied for (give number in each box).	Trademark	0
	Registered design	0
	Other	0
17. How many spin-off companies were created / are planned as a direct result of the project?	0	
<i>Indicate the approximate number of additional jobs in these companies:</i>		
18. Please indicate whether your project has a potential impact on employment, in comparison with the situation before your project:		
<ul style="list-style-type: none"> <input type="checkbox"/> Increase in employment, or <input type="checkbox"/> Safeguard employment, or <input type="checkbox"/> Decrease in employment, <input type="checkbox"/> Difficult to estimate / not possible to quantify 	<ul style="list-style-type: none"> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> 	<ul style="list-style-type: none"> In small & medium-sized enterprises In large companies None of the above / not relevant to the project
19. For your project partnership please estimate the employment effect resulting directly from your participation in Full Time Equivalent (FTE = one person working fulltime for a year) jobs:	<i>Indicate figure:</i> 0	

⁶ Open Access is defined as free of charge access for anyone via Internet.

⁷ For instance: classification for security project.

Difficult to estimate / not possible to quantify

I Media and Communication to the general public

20. As part of the project, were any of the beneficiaries professionals in communication or media relations?

Yes No

21. As part of the project, have any beneficiaries received professional media / communication training / advice to improve communication with the general public?

Yes No

22 Which of the following have been used to communicate information about your project to the general public, or have resulted from your project?

<input checked="" type="checkbox"/> Press Release	<input checked="" type="checkbox"/> Coverage in specialist press
<input checked="" type="checkbox"/> Media briefing	<input checked="" type="checkbox"/> Coverage in general (non-specialist) press
<input checked="" type="checkbox"/> TV coverage / report	<input checked="" type="checkbox"/> Coverage in national press
<input checked="" type="checkbox"/> Radio coverage / report	<input type="checkbox"/> Coverage in international press
<input checked="" type="checkbox"/> Brochures /posters / flyers	<input checked="" type="checkbox"/> Website for the general public / internet
<input checked="" type="checkbox"/> DVD /Film /Multimedia	<input checked="" type="checkbox"/> Event targeting general public (festival, conference, exhibition, science café)

23 In which languages are the information products for the general public produced?

<input checked="" type="checkbox"/> Language of the coordinator	<input checked="" type="checkbox"/> English
<input checked="" type="checkbox"/> Other language(s)	

Question F-10: Classification of Scientific Disciplines according to the Frascati Manual 2002 (Proposed Standard Practice for Surveys on Research and Experimental Development, OECD 2002):

FIELDS OF SCIENCE AND TECHNOLOGY

1. NATURAL SCIENCES

- 1.1 Mathematics and computer sciences [mathematics and other allied fields: computer sciences and other allied subjects (software development only; hardware development should be classified in the engineering fields)]
- 1.2 Physical sciences (astronomy and space sciences, physics and other allied subjects)
- 1.3 Chemical sciences (chemistry, other allied subjects)
- 1.4 Earth and related environmental sciences (geology, geophysics, mineralogy, physical geography and other geosciences, meteorology and other atmospheric sciences including climatic research, oceanography, vulcanology, palaeoecology, other allied sciences)
- 1.5 Biological sciences (biology, botany, bacteriology, microbiology, zoology, entomology, genetics, biochemistry, biophysics, other allied sciences, excluding clinical and veterinary sciences)

2 ENGINEERING AND TECHNOLOGY

- 2.1 Civil engineering (architecture engineering, building science and engineering, construction engineering, municipal and structural engineering and other allied subjects)
- 2.2 Electrical engineering, electronics [electrical engineering, electronics, communication engineering and systems, computer engineering (hardware only) and other allied subjects]
- 2.3 Other engineering sciences (such as chemical, aeronautical and space, mechanical, metallurgical and materials engineering, and their specialised subdivisions; forest products; applied sciences such as

geodesy, industrial chemistry, etc.; the science and technology of food production; specialised technologies of interdisciplinary fields, e.g. systems analysis, metallurgy, mining, textile technology and other applied subjects)

3. MEDICAL SCIENCES

- 3.1 Basic medicine (anatomy, cytology, physiology, genetics, pharmacy, pharmacology, toxicology, immunology and immunohaematology, clinical chemistry, clinical microbiology, pathology)
- 3.2 Clinical medicine (anaesthesiology, paediatrics, obstetrics and gynaecology, internal medicine, surgery, dentistry, neurology, psychiatry, radiology, therapeutics, otorhinolaryngology, ophthalmology)
- 3.3 Health sciences (public health services, social medicine, hygiene, nursing, epidemiology)

4. AGRICULTURAL SCIENCES

- 4.1 Agriculture, forestry, fisheries and allied sciences (agronomy, animal husbandry, fisheries, forestry, horticulture, other allied subjects)
- 4.2 Veterinary medicine

5. SOCIAL SCIENCES

- 5.1 Psychology
- 5.2 Economics
- 5.3 Educational sciences (education and training and other allied subjects)
- 5.4 Other social sciences [anthropology (social and cultural) and ethnology, demography, geography (human, economic and social), town and country planning, management, law, linguistics, political sciences, sociology, organisation and methods, miscellaneous social sciences and interdisciplinary, methodological and historical S1T activities relating to subjects in this group. Physical anthropology, physical geography and psychophysiology should normally be classified with the natural sciences].

6. HUMANITIES

- 6.1 History (history, prehistory and history, together with auxiliary historical disciplines such as archaeology, numismatics, palaeography, genealogy, etc.)
- 6.2 Languages and literature (ancient and modern)
- 6.3 Other humanities [philosophy (including the history of science and technology) arts, history of art, art criticism, painting, sculpture, musicology, dramatic art excluding artistic "research" of any kind, religion, theology, other fields and subjects pertaining to the humanities, methodological, historical and other S1T activities relating to the subjects in this group]