

Dissemination plan

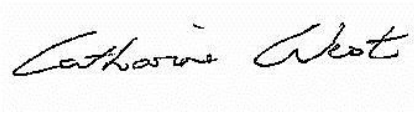
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0 Document history

0.1 Authors

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0.2 Document history

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1 Document Summary

This document describes the plan for disseminating the knowledge and results generated in the REQUIRE project. Various means will be used for dissemination, including the REQUIRE public website, publications in peer-reviewed scientific journals, and participation in scientific conferences and other meetings. It describes the overall strategy for the dissemination of the REQUIRE results and the exploitation plans for the consortium as a whole and for individual participants.

This document will be maintained throughout the lifetime of the project. It is therefore a living document, meaning that it will be updated during the project. It has several purposes:

- to document the overall strategy for the dissemination of the knowledge arising from the REQUIRE project.
- to document the products that will be disseminated and the target audiences
- to document the publication policy within REQUIRE

The final dissemination plan will include guidelines on how the outputs and results of the REQUIRE project could be used by the:

- Research Community
- Radiotherapy Community
- Industrial Community

The REQUIRE dissemination plan will be used not only by the consortium, but also will be placed on the public website so that third parties can view both completed and scheduled dissemination activities.

2 Introduction

2.1 Project Summary

The REQUIRE project aims to validate predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality-of-life in cancer survivors.

Recently the first replicated genetic associations for adverse reactions to radiotherapy were reported. Predictive clinical models for radiotherapy side effects are also being developed. It is now timely to start a project that aims to validate known clinical and genetic predictors of adverse reactions and develop the statistical models for clinical use. REQUIRE is a European Union funded FP7 project aiming to validate clinical models and biomarkers of radiotherapy toxicity and design future trials using the models.

Objectives

The objectives of the REQUIRE study are:

1. Perform a multi-centre, cohort study collecting: blood samples, epidemiology and treatment data, and longitudinal side-effect and quality-of-life data (before and after treatment, years 1 & 2) in 5,300 patients with prostate, breast or lung cancer.
2. Produce a centralised biobank of DNA and a centralised database including radiotherapy plans.
3. Validate published biomarkers of radiosensitivity – genetic and apoptosis assays.
4. Validate clinical predictive models of radiotherapy toxicity in breast, prostate and lung cancer and incorporate biomarker data.
5. Design interventional trials to reduce long-term side-effects.
6. Provide a resource for dissemination and exploitation to the radiotherapy community.

Workflow

Figure 1 presents the workflow of the REQUIRE observational study.

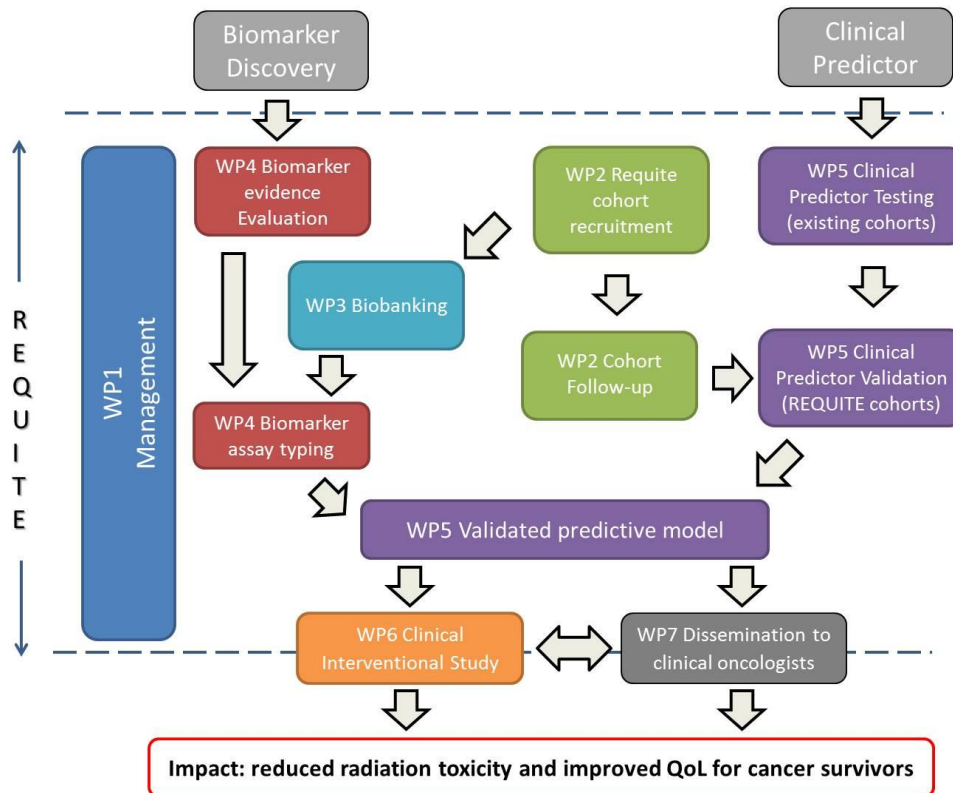


Figure 1. Workflow of the REQUIRE study.

Biomarkers

All 5,300 samples will be genotyped for Single Nucleotide Polymorphism (SNPs) and Copy Number Variation (CNVs) with evidence for association with radiotherapy toxicity. Scale will depend upon costs in project year 5.

In total, 1,800 samples will be assayed for radiation-induced lymphocyte apoptosis using Fluorescence Activated Cell Sorting (FACS) analysis.

Time schedule

The time schedule of the REQUIRE study:

Project start:	Oct 2013
Recruitment starts:	Apr 2014
Recruitment ends:	Mar 2016
Follow-up ends:	Mar 2018
Project complete:	Sep 2018

Partners

Partners of the REQUITE observational study are presented in Figure 2.

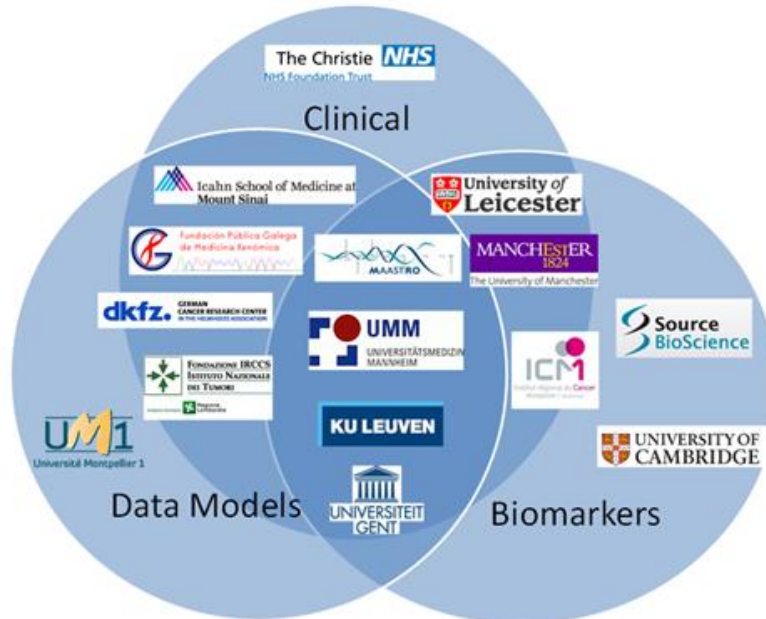


Figure 2. Overview partners of the REQUITE study

Current Status (10 June 2014)

1. Observational study protocol finalised; ethical approval either obtained (France, Germany, Italy, Spain, UK, USA) or pending (Belgium).
2. Standardised case report forms finalised and the first version of the OpenClinica database tested.
3. Questionnaires for collecting patient reported toxicity translated into multiple languages, and back translations completed to check for consistency. The translated questionnaires are being tested in small groups of patients.
4. Bar-coded blood sample kits for blood collection and shipment prepared; standard operating procedures for blood collection, sample shipping and breast photographic assessments finalised.
5. Site initiation visits by German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ) and the Centre for Integrated Genomic Medical Research (CIGMR) are underway.

6. The first patient has been recruited in: Mount Sinai Hospital (New York, USA) on 10th April; The National Cancer Institute of Milan (Italy) on 24th April; the University Hospitals of Leicester (UK) on 28th April; Hospital Clínico Universitario de Santiago de Compostela (Spain) on 20th May, and at Vall d’Hebron (Barcelona, Spain) on 4th June.

7. Apoptosis assay standardised operating procedure completed and inter-laboratory testing begun (Leicester, Mannheim, Montpellier).

8. Breast cancer cohorts for clinical model validation collected and validation of literature reported risk factors, association and prediction statistical modelling for late side-effects applied to the Cambridge IMRT trial data.

9. First version of website developed (www.requite.eu).

Table 1. Overview of the REQUIRE observational study

STUDY SUMMARY	
STUDY DESIGN	Observational/ cohort study
TARGET DISEASE	Cancer of the breast, prostate or lung
PRIMARY STUDY OBJECTIVE	To establish a prospective cohort of patients undergoing radiotherapy for breast, prostate or lung cancer according to local regimens and collecting standardised radiotherapy toxicity data, non-genetic risk factor data and samples for biomarker assays for the study of determinants of radiotherapy side-effects.
SECONDARY STUDY OBJECTIVES	To establish a comprehensive centralised database and sample collection as a resource for the prospective evaluation and validation of clinical models incorporating biomarker data to identify before treatment those cancer patients who are at risk of developing long term side-effects from radiotherapy.
PRIMARY ENDPOINTS	<ul style="list-style-type: none"> • Change in breast appearance at 24 months following start of radiotherapy (breast) • Rectal bleeding at 24 months following start of radiotherapy (prostate) • Dyspnoea/ breathlessness at 12 months following start of radiotherapy (lung)
SECONDARY ENDPOINTS	<ul style="list-style-type: none"> • Other toxicity endpoints including but not limited to: fibrosis, induration and vascular changes (breast); rectal incontinence, urinary toxicity and erectile dysfunction (prostate); dysphagia and esophagitis (lung) • Quality of life • Maximum grade of toxicity during follow-up period

STUDY POPULATION	Male or female patients over 18 years of age with primary cancer of the breast, prostate or lung who are going to receive planned radical radiotherapy or adjuvant radiotherapy after breast conserving surgery or prostatectomy.
RECRUITMENT TARGET	5,300 cancer patients over a 24 month accrual period
FOLLOW UP VISITS	<p>Toxicity will be assessed and documented using REQUIRE toxicity questionnaires based on the Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 and the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life at the following time points. Some site specific questionnaires will be used.</p> <ul style="list-style-type: none"> • Baseline assessed prior to radiotherapy (all) • End of radiotherapy (breast and prostate); or first follow-up visit following implantation for prostate brachytherapy patients • 3 months from start of radiotherapy (lung) • 6 months from start of radiotherapy (lung) • 12 months from start of radiotherapy (all) • 24 months from start of radiotherapy (all) <p>The follow-up period can be extended beyond 24 months. Further follow-up will be permissible and encouraged where possible as part of routine clinical care.</p>
STUDY DURATION	<p>Minimum 24 months but actual follow-up period will depend on time of consent and duration of routine follow-up available at the recruiting centre (see follow-up visits)</p> <p>4 years overall (24 months recruitment period, 24 months minimum follow-up period)</p>
SAMPLE COLLECTION	<p>Pre-treatment blood samples will be collected for downstream analyses:</p> <ul style="list-style-type: none"> - Sample A: one 10ml EDTA sample for DNA extraction to investigate genetic variation as a predictor of radiotherapy toxicity (n~5,300). Depending on the recruiting site further samples can include: - Sample B: a 2.5ml PAXgene sample for future RNA collection and storage (n~3,500) - Sample C: a 10ml Lithium Heparin (LiH) sample for live cell apoptosis assays (n~1,800). Repeat LiH samples will be collected from a sub-set of patients at University of Leicester only (n=200 max).

3 Dissemination Strategy

One of the objectives of REQUIRE is to deliver a resource for dissemination and exploitation within the radiotherapy research community. In order for dissemination to be effective and provide recognisable results, clear definitions of the objectives, products, audiences and means for communication, should be defined.

3.1 Dissemination Objectives

The main objective is the provision of appropriate and reliable information about the scope of REQUIRE, and its resources and results. This dissemination is important in order to optimise data collection methods and data sharing from the REQUIRE database, not only by project partners but also more widely within the radiotherapy research community.

The REQUIRE database has a potentially wider application. The resource can be used to explore the relationships between different radiotherapy side-effect endpoints, and between the endpoints and quality-of-life items. It can also be used to increase knowledge of the health burden of long-term side-effects following radiotherapy in the EU. The centralised biobank and patient samples linked to clinical data has a potential for exploitation in further studies (involving, e.g., next generation sequencing) aimed at increasing the understanding of the biological basis of radiosensitivity.

To exploit the potential of the REQUIRE database fully, it is crucial that information about the project is shared in a comprehensive manner, tailored to the specific needs of the target groups. Therefore, one of the main goals of dissemination activities will be to communicate the relevant products at different levels, thus aiming at higher penetration and exploitation of the resources, knowledge and results from REQUIRE.

3.3 REQUIRE Target Groups

The target groups for REQUIRE dissemination include the following:

- The **Radiotherapy Community (RC)**: with the aim to: raise awareness regarding the REQUIRE objectives and results; increase use of standardised data collection forms; and encourage collaborations.
- The **Scientific Community (SC)**: with the aim to spread the scientific results and promoting their use in other research areas as well (e.g. health economics).

- The **Industrial Community (IC)**: with the aim to communicate and promote the results to technology providers.
- The **Radiotherapy Patients Community (RPC)**: with the aim to communicate the REQUIRE objectives and results to patients, and raise overall awareness of the project.
- The **General Public (GP)**: with the aim to raise overall awareness of the project and the REQUIRE objectives and results.

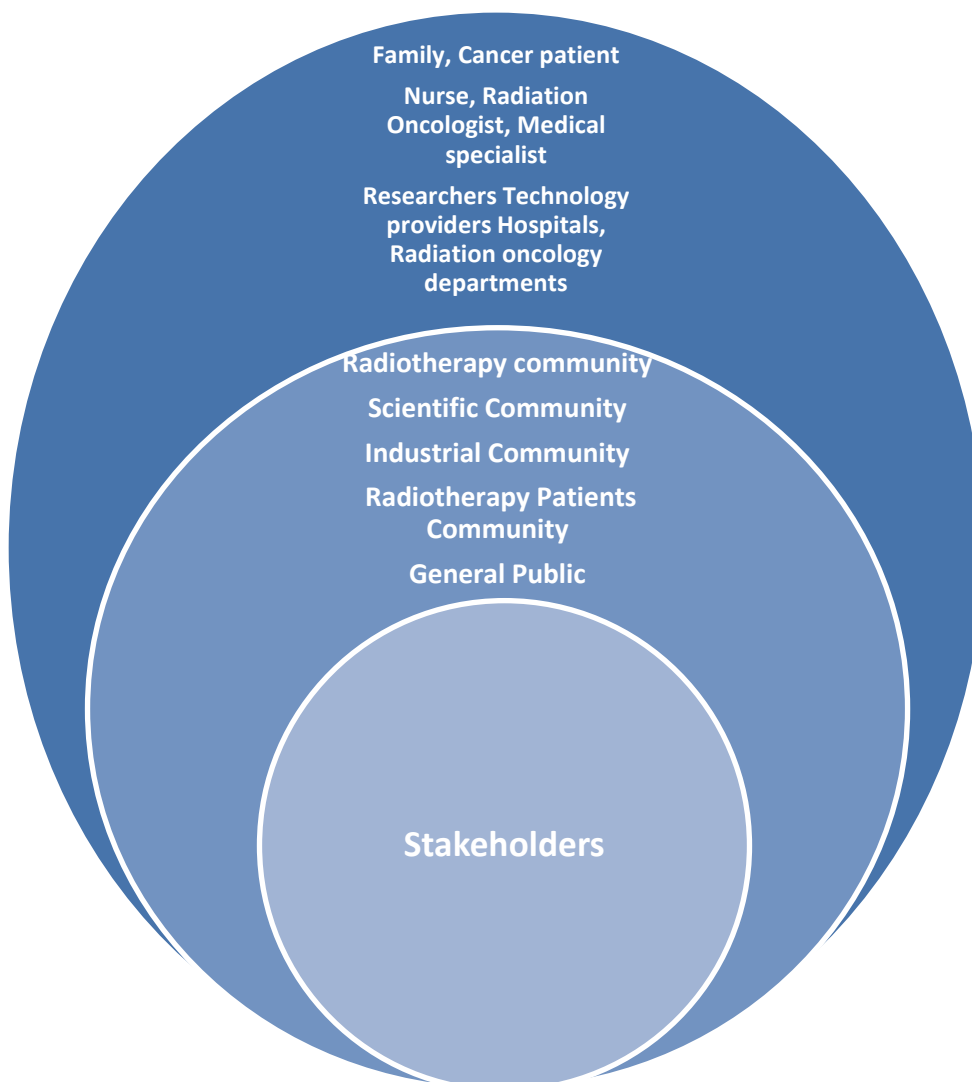


Figure 3: REQUIRE target group

To ensure effective dissemination, multiple communication channels are considered. For REQUIRE, the following **means** have been identified:

1. The project website, <http://www.requite.eu>, which will be updated regularly.
2. Press releases in various media announcing the start of the project and key achievements.
3. Abstract, poster and powerpoint presentation at conferences and meetings, incorporating the project logo and acknowledgement of EC-funding, ensuring uniform presentation of the project.
4. Promotional material, including brochures etc., which will be sent to all partners for further distribution through their networks.
5. Project presentations at related events, workshops and conferences as results become available.
6. Publications in peer reviewed scientific journals.
7. General press.
8. Round table events with patient advocacy groups to inform patients on the progress and developments within the project, and receive patient feedback and insights.
9. (Monthly) Telephone conferences to keep a track of abstracts submitted, posters/talks presented.
10. Annual REQUIRE meeting and a final REQUIRE international conferences after the end of the data-collection but before the end of the final reporting.

3.3 Dissemination products

For dissemination, several products will be developed; all the products will use the REQUIRE logo (see Annex 6.1) and European Union logo (see Annex 6.2). Whenever practical, the products will acknowledge funding from the European Union's Seventh Framework Programme.

- The **REQUIRE website** (see Annex 6.3 for screenshot of home page). The website will be open access. The website will be the main dissemination product, aiming at providing information on the REQUIRE project, for patients, the scientific

community, as well as for the public. Part of the website will contain information for the scientific community (see Annex 6.4 for screen shot). The wording used will be less general and more scientific.

- The **REQUIRE Biobank** module on the website: this module will be aimed towards (i) patients interested in following the progress of the study, and (ii) at a later stage third parties wanting to request use of samples from the REQUIRE biobank. Within this module a request procedure will be described for submitting proposals (side-project) using samples from the REQUIRE biobank.
- The **REQUIRE Case Report Forms (CRF)** tool on the website: this product will allow interested third parties to make use of the Case Report Forms that were developed as part of the REQUIRE project.
- The **REQUIRE Project Deliverables** (see Annex 6.5): the project deliverables will be reported to the EC via the Participant Portal.
- **REQUIRE (scientific) Publications:** scientific publications in peer-reviewed journals will inform the scientific community on the design, progress and results of the REQUIRE project. Press releases will be used to inform the general public about REQUIRE. An overview of these products will be available and regularly updated on the REQUIRE website.
REQUIRE abstracts, PowerPoint presentations and posters: use of standardised formats (see Annex 6.6, 6.7 and 6.8) will allow for consistent reporting of the results in a comprehensive manner to targeted users.

Table 2. Overview of dissemination products and target groups

Dissemination products	Target group*	Means
Project description	RC, SC, IC, RPC, GP	1, 2, 4, 5, 6, 7, 8
Biobank Module	RC, SC, IC	1, 5, 7
Case Report Forms	RC, SC, IC	1, 3, 5, 10
Project deliverables	RC, SC, IC, RPC, GP	1, 3, 5, 9, 10
Scientific publications	RC, SC, IC	1, 2, 5, 6, 7, 9, 10

* RC: Radiotherapy Community; SC: Scientific Community; IC: Industrial Community; RPC: Radiotherapy Patients Community and GP: General Public

4. Dissemination Activities

4.1 Events, conferences or workshops

Events, conferences and/or workshops will be published on the REQUIRE website and reported through the Participant Portal.

4.2 Publication Policy

For the main publication(s) of this study, it is anticipated that all contributors will be authors with the proviso that clinicians must have contributed at least 20 patients. A formal publications policy will be generated, to which all participants will be asked to agree.

The main results of the REQUIRE study will be published in (high impact) peer-reviewed journals, on behalf of all collaborators. The manuscript will be prepared by the first author, the Steering Committee, and high accruing clinicians. All recruiting study centres and clinicians will be acknowledged in the publications. All presentations and publications relating to the study must be authorised by the Steering Committee. No investigator may present or attempt to publish data relating to REQUIRE without prior permission from the Steering Committee. The digital pdf-files of the final publications will be sent to the dissemination manager for publication on the REQUIRE website.

Table 3. Examples of targeted Scientific Journals

Title	Type of Journal	Impact Factor [*]
Radiotherapy Oncology	Peer-reviewed, scientific journal	4.520
European Journal of Cancer	Peer-reviewed, scientific journal	5.061
BMC Cancer	Peer-reviewed, scientific journal, open access	3.330

^{*} Impact Factors quoted from 2013 JCR Science Edition.

4.3 Project Website

As a central point for dissemination, the REQUIRE project website will be developed under <http://www.require.eu>. This website will contain information about the project, the objectives, the project partners, progress to date, news, and upcoming relevant events. The public area of the website will be divided into an area aimed at the scientific

community. This area will include, amongst others, information on the protocol, downloadable Case Report Forms, an overview of publications and press releases. The general public area of the website is aimed towards patients advocacy groups and the general public, and will contain amongst others, project information and public press releases. In addition, the website will have areas targeted at research but open access to ensure transparency of dissemination. The website will be updated regularly.

Annex 6.3 and 6.4 contain representative screenshots of the REQUIRE website. The structure is summarized below:

- For patients and other members of the public:
 - Home page (About..., News, Calendar)
 - Project information (in several languages)
 - Objectives and approach in general wording, links to information about cancer and radiotherapy, patient information sheet.
 - The questionnaires for collecting patients reported toxicity
 - Website links about radiotherapy, cancer and EORTC Quality of Life questionnaires.
 - Overview publications
- For the wider scientific community:
 - Home page (About..., News, Calendar)
 - Project information (in UK language)
 - Objectives, approach, time scale, work flow, description about the workpackpages in scientific wording.
 - The questionnaires for collecting patients reported toxicity and information on the development of the questionnaires
 - The observational study protocol
 - The case report forms
 - Patient information sheet in all languages
 - Dissemination plan, including
 - REQUIRE template posters
 - REQUIRE template presentation
 - REQUIRE Logo
 - Overview publications

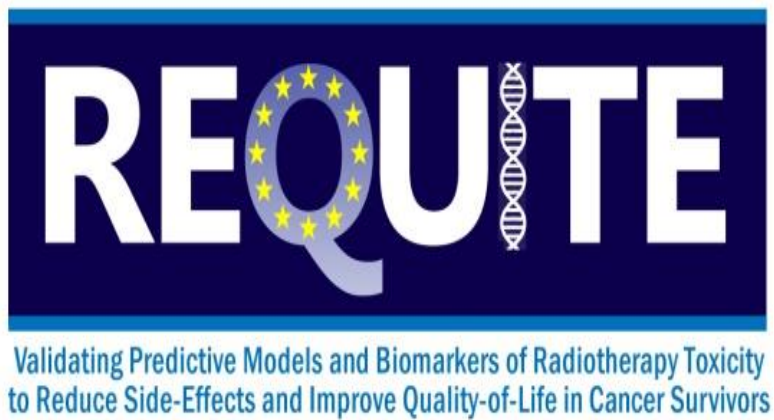


5 Legal framework

Any intellectual property rights, generated within the framework of the REQUIRE project, are covered by the Consortium Agreement.

6 Annexes

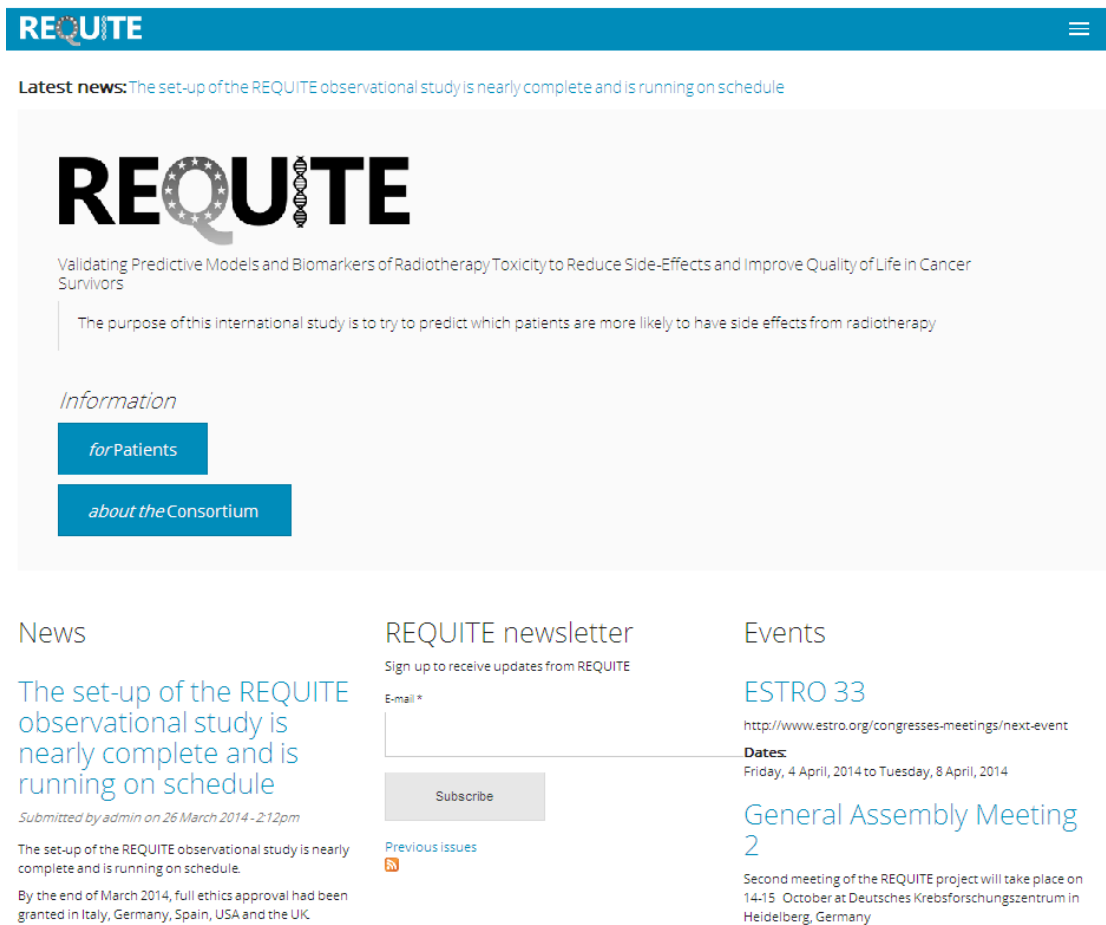
6.1 Project Logo



6.2 Logo European Union



6.3 Project website: Home Page



REQUIRE

Latest news: The set-up of the REQUIRE observational study is nearly complete and is running on schedule

REQUIRE

Validating Predictive Models and Biomarkers of Radiotherapy Toxicity to Reduce Side-Effects and Improve Quality of Life in Cancer Survivors

The purpose of this international study is to try to predict which patients are more likely to have side effects from radiotherapy

Information

[for Patients](#)

[about the Consortium](#)

News

The set-up of the REQUIRE observational study is nearly complete and is running on schedule

Submitted by admin on 26 March 2014 - 2:12pm

The set-up of the REQUIRE observational study is nearly complete and is running on schedule.


By the end of March 2014, full ethics approval had been granted in Italy, Germany, Spain, USA and the UK

REQUIRE newsletter

Sign up to receive updates from REQUIRE

E-mail *

[Previous issues](#)



Events

ESTRO 33

<http://www.estro.org/congresses-meetings/next-event>

Dates:
Friday, 4 April, 2014 to Tuesday, 8 April, 2014

General Assembly Meeting 2

Second meeting of the REQUIRE project will take place on 14-15 October at Deutsches Krebsforschungszentrum in Heidelberg, Germany

6.4 Project website: Scientific Community area

<Screen shot>

6.5 Project deliverable front cover sheet



PROJECT DELIVERABLE



Project acronym: REQUIRE	GA number: 601826
Project title: Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality-of-life in cancer survivors	
Funding Scheme: Collaborative Project (FP7-HEALTH-2013-INNOVATION-1)	
Project start date: 01 October 2013	Duration: 60 months
Project's coordinator: Prof Catharine West (University of Manchester, UK)	

Deliverable no.:	Title:
Due date:	Actual date:
Aim of the Deliverable:	
Lead beneficiary for this deliverable:	
Personnel involved:	

Dissemination level:		
PU	Public	
PP	Restricted to other programme participants (within the Commission)	
RE	Restricted to a group defined by the consortium (including the Commission)	
CO	Confidential, only for members of the consortium (including the Commission)	

6.6 Project Abstract Template

Title:

"The REQUIRE project: validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects"

Authors:

Tiziana Rancati (Fondazione IRCCS Istituto Nazionale dei Tumori, Milan), Christopher Talbot (University of Leicester), David Azria (University of Montpellier), Anthony Brookes (University of Leicester), Tom Burr (Source Bioscience, Nottingham), Jenny Chang-Claude (German Cancer Research Centre (DKFZ), Heidelberg), Susan Davidson (The Christie NHS Foundation Trust, Manchester), Dirk De Ruysscher (University Hospitals Leuven/KU Leuven), Alison Dunning (University of Cambridge), Rebecca Elliott (University of Manchester), Sara Gutiérrez Enríquez (Vall d'Hebron Institute of Oncology-VHIO, Barcelona), Philippe Lambin (Stichting Maastricht Radiation Oncology (MAASTRO), Maastricht), Laura Lozza (Fondazione IRCCS Istituto Nazionale dei Tumori, Milan), Barry Rosenstein (Mount Sinai School of Medicine, New York), R. Paul Symonds (University of Leicester), Hubert Thierens (Universiteit Gent), Riccardo Valdagni (Fondazione IRCCS Istituto Nazionale dei Tumori, Milan), Ana Vega (Fundación Pública Galega Medicina Xenómica, Santiago de Compostela), Frederik Wenz (German Cancer Research Centre (DKFZ), Heidelberg), Martin Yuille (University of Manchester), Catharine West (University of Manchester)


Background:

"REQUIRE is a European Union funded FP7 project."

REQUIRE's objectives:**Methods:****Results:****Conclusion and/or Discussion:****Acknowledgements:**

"This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no. 601826."


6.7 Project PowerPoint Presentation Template



Validating Predictive Models and Biomarkers of Radiotherapy Toxicity
to Reduce Side-Effects and Improve Quality-of-Life in Cancer Survivors

**REQUIRE: Validating predictive models and biomarkers of radiotherapy toxicity to
reduce side-effects and improve quality-of-life**

Name of the presenter



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*This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no. 601626.

Title

Acknowledgements






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6.8 Project Poster Template

REQUIRE: Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality-of-life	
<p>Dirk De Ruyscher¹, Christopher Talbot², David Azria³, Anthony Brookes⁴, Adam Webb⁵, Tom Burr⁶, Jenny Chang-Claude⁷, Petra Seibold⁸, Susan Davidson⁹, Anusha Appenve¹⁰, Alison Dunning¹¹, Rebecca Elliott¹², Sara Gutiérrez Enriquez¹³, Philippe Lambin¹⁴, Laura Lozza¹⁵, Tatiana Rancati¹⁶, Barry Rosenstein¹⁷, R. Paul Symonds¹⁸, Hubert Thalerens¹⁹, Riccardo Valdagni²⁰, Ana Vega²¹, Frederik Wenz²², Martin Yulle²³, Genevieve Pridham²⁴, Kate Dixon²⁵ and Catharine West²⁶</p> <p><small>¹University Hospitals Leuven/KU Leuven, ²University of Leicester, ³University of Montpellier, ⁴Source Bioscience, ⁵German Cancer Research Centre (DKFZ), ⁶The Christie NHS Foundation Trust, ⁷University of Cambridge, ⁸University of Manchester, ⁹Radiation Therapy Institute of Oncology (RTO), Barcelona, ¹⁰Stirling (Massachusetts) Radiation Oncology (Massmo), ¹¹Fondación Pública Galega de Medicina, ¹²Fondazione RCOG (Italy), ¹³Nazionale de Tumor, ¹⁴Mount Sinai School of Medicine, New York, ¹⁵Université de Saint</small></p>	
INTRODUCTION	OBJECTIVES
<p>REQUIRE is a European Union funded FP7 project aiming to validate clinical models and biomarkers of radiotherapy toxicity and design future trials using the models.</p>	
METHODS	RESULTS
CONCLUSION/ DISCUSSION	PARTNERS
	
ACKNOWLEDGEMENT	
<p><small>*This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement no. 601826.</small></p>	
<div>  <div> www.require.eu require@manchester.ac.uk </div>  </div> <p><small>Validating Predictive Models and Biomarkers of Radiotherapy Toxicity to Reduce Side-Effects and Improve Quality-of-Life in Cancer Survivors</small></p>	