# Dissemination plan

<table>
<thead>
<tr>
<th>Project funded by the European Commission within the Seventh Framework Program</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Grant agreement No.</strong></td>
</tr>
<tr>
<td><strong>Start date of project</strong></td>
</tr>
<tr>
<td><strong>Duration</strong></td>
</tr>
<tr>
<td><strong>Nature</strong></td>
</tr>
<tr>
<td><strong>Dissemination Level</strong></td>
</tr>
<tr>
<td><strong>Date</strong></td>
</tr>
<tr>
<td><strong>Author(s)</strong></td>
</tr>
</tbody>
</table>

**Document description**

This sets out the REQUITE plan for dissemination activities towards the promotion of the research results to the scientific community and the general public.
Dissemination Plan
WP 7
Version 0.3

0 Document history

0.1 Authors

<table>
<thead>
<tr>
<th>Authors</th>
<th>Company</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
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</tr>
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</tr>
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<td>Maastro Clinic</td>
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</tr>
</tbody>
</table>

0.2 Document history

<table>
<thead>
<tr>
<th>Document version</th>
<th>Date</th>
<th>Change</th>
</tr>
</thead>
</table>
| Version 0.1      | 10/1/2014 | MAASTRO Clinic  
|                  |         | Kim Smits(KS) 
|                  |         | Vivian Braeken (VB)                                                   |
| Version 0.2      | 29/4/2014 | MAASTRO Clinic  
|                  |         | Kim Smits(KS) 
|                  |         | Vivian Braeken (VB)                                                   
|                  |         | Version after review                                                  |
| Version 0.3      | 9/6/2014  | MAASTRO Clinic  
|                  |         | Kim Smits(KS) 
|                  |         | Vivian Braeken (VB)                                                   
|                  |         | Version after review members of Steering Committee                   |
| Sign off         | 11/06/14 | Signed off version by: REQUITE Co-ordinator  
|                  |         | Prof. dr. C. West  
|                  |         | Signature:                                                             |
|                  |         | ![Signature Image]                                                     |
| Version 1.0      | 11/06/14 | Approved Version to be submitted to EU                                |
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1 Document Summary

This document describes the plan for disseminating the knowledge and results generated in the REQUITE project. Various means will be used for dissemination, including the REQUITE 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 REQUITE 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 REQUITE project.
- to document the products that will be disseminated and the target audiences
- to document the publication policy within REQUITE

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

- Research Community
- Radiotherapy Community
- Industrial Community

The REQUITE 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 REQUITE 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. REQUITE 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 REQUITE 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.


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 REQUITE observational study.

Figure 1. Workflow of the REQUITE 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 REQUITE 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.

![Diagram showing REQUITE study partners]

**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 10<sup>th</sup> April; The National Cancer Institute of Milan (Italy) on 24<sup>th</sup> April; the University Hospitals of Leicester (UK) on 28<sup>th</sup> April; Hospital Clínico Universitario de Santiago de Compostela (Spain) on 20<sup>th</sup> May, and at Vall d’Hebron (Barcelona, Spain) on 4<sup>th</sup> 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.


Table 1. Overview of the REQUITE observational study

<table>
<thead>
<tr>
<th>STUDY SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STUDY DESIGN</strong></td>
</tr>
<tr>
<td>Observational/ cohort study</td>
</tr>
<tr>
<td><strong>TARGET DISEASE</strong></td>
</tr>
<tr>
<td>Cancer of the breast, prostate or lung</td>
</tr>
<tr>
<td><strong>PRIMARY STUDY OBJECTIVE</strong></td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>SECONDARY STUDY OBJECTIVES</strong></td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td><strong>PRIMARY ENDPOINTS</strong></td>
</tr>
<tr>
<td>• Change in breast appearance at 24 months following start of radiotherapy (breast)</td>
</tr>
<tr>
<td>• Rectal bleeding at 24 months following start of radiotherapy (prostate)</td>
</tr>
<tr>
<td>• Dyspnoea/ breathlessness at 12 months following start of radiotherapy (lung)</td>
</tr>
<tr>
<td><strong>SECONDARY ENDPOINTS</strong></td>
</tr>
<tr>
<td>• 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)</td>
</tr>
<tr>
<td>• Quality of life</td>
</tr>
<tr>
<td>• Maximum grade of toxicity during follow-up period</td>
</tr>
<tr>
<td>STUDY POPULATION</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>RECRUITMENT TARGET</td>
</tr>
</tbody>
</table>
| FOLLOW UP VISITS   | Toxicity will be assessed and documented using REQUITE 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.  
  - 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)  
  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. |
| STUDY DURATION     | 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)  
  4 years overall (24 months recruitment period, 24 months minimum follow-up period) |
| SAMPLE COLLECTION  | Pre-treatment blood samples will be collected for downstream analyses:  
  - 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 REQUITE 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 REQUITE, and its resources and results. This dissemination is important in order to optimise data collection methods and data sharing from the REQUITE database, not only by project partners but also more widely within the radiotherapy research community.

The REQUITE 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 REQUITE 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 REQUITE.

3.3 REQUITE Target Groups

The target groups for REQUITE dissemination include the following:

- The **Radiotherapy Community (RC)**: with the aim to: raise awareness regarding the REQUITE 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).
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- 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 REQUITE 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 REQUITE objectives and results.

Figure 3: REQUITE target group
To ensure effective dissemination, multiple communication channels are considered. For REQUITE, 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.


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 REQUITE meeting and a final REQUITE 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 REQUITE 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 REQUITE 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 REQUITE 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 REQUITE 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 REQUITE biobank. Within this module a request procedure will be described for submitting proposals (side-project) using samples from the REQUITE biobank.

- **The REQUITE 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 REQUITE project.

- **The REQUITE Project Deliverables** (see Annex 6.5): the project deliverables will be reported to the EC via the Participant Portal.

- **REQUITE (scientific) Publications**: scientific publications in peer-reviewed journals will inform the scientific community on the design, progress and results of the REQUITE project. Press releases will be used to inform the general public about REQUITE. An overview of these products will be available and regularly updated on the REQUITE website. REQUITE 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

<table>
<thead>
<tr>
<th>Dissemination products</th>
<th>Target group*</th>
<th>Means</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project description</td>
<td>RC, SC, IC, RPC, GP</td>
<td>1, 2, 4, 5, 6, 7, 8</td>
</tr>
<tr>
<td>Biobank Module</td>
<td>RC, SC, IC</td>
<td>1, 5, 7</td>
</tr>
<tr>
<td>Case Report Forms</td>
<td>RC, SC, IC</td>
<td>1, 3, 5, 10</td>
</tr>
<tr>
<td>Project deliverables</td>
<td>RC, SC, IC, RPC, GP</td>
<td>1, 3, 5, 9, 10</td>
</tr>
<tr>
<td>Scientific publications</td>
<td>RC, SC, IC</td>
<td>1, 2, 5, 6, 7, 9, 10</td>
</tr>
</tbody>
</table>

*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 REQUITE 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 REQUITE 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 REQUITE without prior permission from the Steering Committee. The digital pdf-files of the final publications will be send to the dissemination manager for publication on the REQUITE website.

Table 3. Examples of targeted Scientific Journals

<table>
<thead>
<tr>
<th>Title</th>
<th>Type of Journal</th>
<th>Impact Factor*</th>
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</thead>
<tbody>
<tr>
<td>Radiotherapy Oncology</td>
<td>Peer-reviewed, scientific journal</td>
<td>4.520</td>
</tr>
<tr>
<td>European Journal of Cancer</td>
<td>Peer-reviewed, scientific journal</td>
<td>5.061</td>
</tr>
<tr>
<td>BMC Cancer</td>
<td>Peer-reviewed, scientific journal, open access</td>
<td>3.330</td>
</tr>
</tbody>
</table>


4.3 Project Website
As a central point for dissemination, the REQUITE project website will be developed under http://www.requite.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 REQUITE 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
    - REQUITE template posters
    - REQUITE template presentation
    - REQUITE Logo
  - Overview publications
5 Legal framework

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

6.1 Project Logo

6.2 Logo European Union
6.3 Project website: Home Page

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

6.4 Project website: Scientific Community area

<Screen shot>
### 6.5 Project deliverable front cover sheet

<table>
<thead>
<tr>
<th><strong>PROJECT DELIVERABLE</strong></th>
</tr>
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</table>

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

<table>
<thead>
<tr>
<th><strong>Deliverable no.:</strong></th>
<th><strong>Title:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Due date:</strong></td>
<td><strong>Actual date:</strong></td>
</tr>
</tbody>
</table>

**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 REQUITE 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:
“REQUITE is a European Union funded FP7 project.”

REQUITE’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

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

Name of the presenter

www.requite.eu
requite@manchester.ac.uk

*This project has received funding from the European Union’s Seventh Framework Programme for research, technological development and demonstration under grant agreement no. 608124.
Acknowledgements


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