



Decision on Optimal Combinatorial  
Therapies in IMIDS using Systems  
Approaches

DocTIS

## Deliverable 9.1

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Author	VHIR



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**INDEX**

- 1. INTRODUCTION ..... 3**
  - 1.1 IMPORTANCE OF THE COMMUNICATION PLAN ..... 3
  - 1.2 ABOUT THE DOCTIS PROJECT ..... 3
  - 1.3 COMMUNICATION PLAN CONDITIONS ..... 4
- 2. COMMUNICATION OBJECTIVES ..... 4**
- 3. TARGET AUDIENCES ..... 5**
- 4. COMMUNICATION CHANNELS ..... 6**
  - 4.1 SCIENTIFIC PUBLICATIONS ..... 6
  - 4.2 CONFERENCES, SCIENTIFIC AND COMMUNITY EVENTS ..... 7
  - 4.3 INDIVIDUAL PRESENTATIONS AND MEETINGS WITH KEY STAKEHOLDERS ..... 7
- 5. COMMUNICATION TOOLS ..... 7**
  - 5.1 PROJECT LOGO ..... 8
  - 5.2 PROJECT WEBSITE ..... 8
- 6. COMMUNICATION STRATEGY ..... 9**
- 7. EVALUATION OF RESULTS ..... 11**
- 8. CRISIS COMMUNICATION ..... 11**
- 9. COMMUNICATION BUDGET ..... 12**

## 1. INTRODUCTION

### 1.1 IMPORTANCE OF THE COMMUNICATION PLAN

Maintaining an adequate level of communication effort will be key to ensuring the sustainability of the project and the optimal delivery of its core operations.

A planned communication will contribute to meet the requirements of the project by leading the DoCTIS Consortium on the desired project outcomes. It will facilitate two-way exchanges between the project participants, external stakeholders and interested parties, and it will steer the public's attention to the key findings and achievements of the project.

Effective communication requires planning and coordination. In order to facilitate the accomplishment of the objectives established, the Communication Plan will provide a framework to structure, control and ensure good project communications, clearly defining:

- Objectives - What DoCTIS wants to achieve with its communications.
- Audiences - To whom these communications will be primarily addressed.
- Channels - Ways in which the communication objectives will be accomplished.
- Tools - Means used by DoCTIS to undertake actions.
- Strategy – The Communication Plan.
- Roles and responsibility – Actions to be taken by the DoCTIS governing bodies and partners.
- Crisis – How to act in a communication crisis situation.
- Evaluation - How DoCTIS will assess the results of its communication activities

### 1.2 ABOUT THE DOCTIS PROJECT

In order to elaborate an effective Communication Plan, it is important to understand the project and its main objectives.

DoCTIS is the acronym for the EU-funded project entitled "Decision on Combinatorial Therapies in Immune-Mediated diseases using Systems approaches". DoCTIS is a multicentric project involving diverse basic, applied and clinical research centres from Spain, Sweden, Italy, Germany, UK and USA, and is aimed at improving treatment efficacy in six Immune-Mediated Inflammatory Diseases (IMIDs). These IMIDs encompass Crohn's disease, ulcerative colitis, rheumatoid arthritis, systemic lupus erythematosus, psoriasis and psoriatic arthritis. Through the generation of high volumes of data using modern high-throughput technologies on samples from well-characterized IMID patients, and the use of advanced systems biology analytical approaches, we aim to identify therapeutic combinations that are much more efficacious and safer than the current single-drug approaches.

The DoCTIS project has been designed to address this important health problem in IMIDs. To do so, we will identify new combinations of existing drugs that potentiate the effect of each other. This combinatorial effect will have many beneficial aspects for IMID patients: it will lower the disease activity down to remission (i.e. free of symptoms), it will allow to reduce drug dosage (and, therefore, reduce the risk of toxicity) and, finally, it will reduce the probability of becoming resistant to the therapy.

### 1.3 COMMUNICATION PLAN CONDITIONS

The envisioned Communication Plan will help raise awareness about the project itself and its results among different stakeholders, whilst retaining flexibility so as to be compatible with changes as the project evolves. The communication plan will allow for a prompt and well-managed response to any significant variation in the project along its life-cycle.

In order to develop a successful communication plan, the following conditions will be ensured:

- **Defined communication objectives:** in order to ensure that messages are complementary and linked as appropriate, communication objectives will be defined at an early stage of the process.
- **Benefits:** the communication plan will focus on the activities that provide clear benefits to the project and its stakeholders. This will require balancing the need for clarity and visibility (e.g. of the benefits expected from the project results) with the need to avoid false expectations or the anticipation of demands from one or more stakeholder groups, especially from patients and patient organisations.
- **Consistency:** the plan will allow for consistent communication activities across the Consortium, at the international, national or local levels. This has already been done for the press release. The official logo and project image have also been used for other dissemination materials and templates.
- **Focus on achievements:** as the project progresses in time, the communication plan will identify channels for publicising achievements in order to ensure that results are appropriately disseminated at local, national, European and international levels.
- **Timeliness:** the communication plan will allow for anticipation of communication opportunities and threats, so that tools and events are well coordinated and effectively managed.
- **Flexibility:** a variety of adaptable tools will be identified for disseminating information, while considering the different needs of the targeted audiences.
- **Complementarity:** the communication plan will use existing tools, such as partners' websites, to ensure a seamless communication interface.

## 2. COMMUNICATION OBJECTIVES

- To secure the commitment of the **key stakeholders** to the project aims by ensuring timely and effective communication between the consortium partners throughout the different phases of the project and work packages.
- To build awareness of the project among a **wide defined group of audiences** allowing them engaging in a two-way dialogue with DocTIS stakeholders – consortium partners, scientific

community, civil society and communities, regulatory authorities and industry - by ensuring effective management of the communication platforms and tools.

- Ensure that **policy and decision makers** at the national and international levels are fully aware of the DoctIS work and project outcomes.
- To ensure that the identified audiences are **aware** (or can be effectively informed) **of the project progress** and deliverables through the continuous, clear and targeted use of relevant dissemination channels.
- To ensure the **correct and consistent use of the communication tools** and the role of the European Commission as the Consortium's funder by providing guidelines and procedures for communication to all consortium partners

### 3. TARGET AUDIENCES

The following target groups, communication channels and types of information required have been pre-identified:

TABLE 1. Target groups for dissemination actions

Target audience	Disseminated message	Dissemination programme
<b>Scientific community, including scientific organizations</b>	Ensure the scientific community is aware of the project and also of work not reflected in scientific publications from which other scientists may benefit. Opportunities to contribute.	Publications in high-impact factor journals /Scientific articles and abstracts / Lectures in scientific venues, including academia, congresses, symposia and workshops/ Invitation of key scientific leaders to final workshop / website of the project ( <a href="http://www.doctis.eu">www.doctis.eu</a> )
<b>Clinical community (including clinical societies)</b>	Ensure the clinical community is aware of the project and the opportunities to benefit and contribute.	Scientific articles and abstracts / Participation of partner members in clinical meetings and symposia / Invitation of key clinical leaders to final workshops / website of the project ( <a href="http://www.doctis.eu">www.doctis.eu</a> )
<b>Participants involved in the clinical trial</b>	Project aims and planning, possible outcomes, consequences of withdrawing from DoctIS.	For the recruitment, adverts will be displayed in hospitals. During and after the clinical trial, participants will be updated on latest information via letter and a digital newsletter (subscription via the clinical site).
<b>People affected by IMID (including patient associations)</b>	Project progress, outcomes and results.	Website, publications, presentations, patient focus groups, brochure, generic poster, social media (Twitter, Facebook).
<b>Purchasers/payers of healthcare systems</b>	Maintain close contact with healthcare providers/users that will eventually manage and cover the cost of treatment.	Scientific articles and abstracts, participation of partner members in scientific meetings and symposia, website, brochure, generic poster, social media (Twitter), press releases
<b>Policy makers and the general public in Europe</b>	Importance and limits of cure research.	Scientific articles and abstracts, website, social media (Twitter, Facebook), press releases
<b>Industry</b>	Biotechnological companies aware of the possibility of co-development of a	Stands in main international biotechnology conventions; face to face meetings with

	companion diagnostic for IMIDs that could be of broad medical use.	pharmaceutical companies interested in companion diagnostics; press notes.
<b>Public at large</b>	At the right time, release information on the key clinical and scientific milestones achieved by the project.	Dissemination to the lay public: Website, publications, social media (Twitter, Facebook), brochure, generic poster, press releases, workshop, seminars.
<b>Healthcare providers: National and regional</b>	Ensure that healthcare providers know the advance in precision medicine for IMIDs, facilitate its adoption in daily clinical routine.	Face to face meetings with decision makers of public and private healthcare organisations.

Clinical trials on combinatorial therapies based on targeted drugs are a novel concept in IMIDs. For this reason, special emphasis will be applied to the dissemination of this novel clinical trial. The [CREATE Centre](#) (partner #4, CARDIFF) will work with the Community Engagement Team at CARDIFF to inform the public about its research and activities. The Community Engagement Team was established in 2006 to work closely with academic staff to disseminate effectively the University's research and knowledge, and to increase public awareness of and engagement with Cardiff's academic specialisms and expertise. The main tasks of CET at CARDIFF will be to support CREATE in:

- Managing partnerships in engagement and coordinating multidiscipline or corporate-level engagement events
- Taking part in engagement activities such as coordinating festivals and Science Cafés.
- Developing a coherent media strategy in liaison with Arthritis Research UK.
- Publishing its latest research in the public media including print, broadcast and online at local, national or international levels to ensure maximum publicity.
- Drafting press releases and setting up media interviews as well as using social media through the Facebook and Twitter Account of the Cardiff University Research Office.

#### 4. COMMUNICATION CHANNELS

The main channels for the communication and dissemination of results are the following:

##### 4.1 SCIENTIFIC PUBLICATIONS

Scientific articles constitute an excellent dissemination instrument to reach a wider scientific audience and to make researchers and clinicians aware of project objectives, activities and results in a detailed manner. Papers will be mainly submitted for publication to peer-reviewed international scientific journals with as high an impact as possible. In that sense, a minimum of 4 articles in journals such as:

- Science Translational Medicine,
- Nature Communications,
- Nature Medicine,
- PLoS Medicine,
- Nature,
- Science.

Publications will follow the requirements of the Article 29.2 of the Grant Agreement on open access of scientific publications related to the Project foreground. This means that the partners will, when possible,

publish via gold-open access. In the rest of cases, a green-open access policy will take place, and the partners will self-archive the publications in a repository where they can be accessed for free. Partners will be encouraged to disseminate the results of their studies after a careful consideration of the patentability of the project innovations, including the suggestions of the Exploitation Board on the non-disclosure of confidential information. All derived publications will acknowledge EU funding.

## 4.2 CONFERENCES, SCIENTIFIC AND COMMUNITY EVENTS

An important dissemination activity will be arranged at national and international levels to involve stakeholders and enhance their awareness, foster cooperation, spread best practices, etc. This will comprise participation in relevant events of the different disciplines where the presentation of the project, its approaches and results, can take place, such as:

- **Rheumatology:** Congress of Rheumatology (EULAR, interview with Prof. Marsal), American College of Rheumatology (ACR, interview with Prof. Marsal, VHIR), British Society of Rheumatology (Prof. Choy), International congress on Systemic Lupus Erythematosus (abstract/poster/oral presentation) and European Lupus Meeting (abstract/poster/oral presentation)
- **Dermatology** (Prof. Girolomoni, VU): American Academy of Dermatology (AAD, abstract/poster/oral presentation), European Academy of Dermatology and Venereology (EADV, abstract/poster/oral presentation)
- **Gastroenterology** (Prof. Siegmund, BER): United European Gastroenterology (UEG, interview with Prof. Marsal), Digestive Disease Week (DDW, abstract/poster/oral presentation Science.

Apart from that, each participation will take place every year until the project will be finished and every partner will be able to participate in the different local or national congresses to disseminate WP results.

## 4.3 INDIVIDUAL PRESENTATIONS AND MEETINGS WITH KEY STAKEHOLDERS

To raise the interest and gain support of key actors in the field, such as regulatory authorities and pharmaceutical companies, individual contacts will be established as needed.

## 5. COMMUNICATION TOOLS

In order to support the objectives and actions described above, different tools are envisaged for the dissemination of the project as press releases, website, brochures, fact sheet, posters and templates.

At this first stage of the project, several dissemination tools have been created in line with the initial communication strategy and the incipient project status:

- Project logo
- Project website
- Press release
- PowerPoint template
- Fact sheet

The Consortium will also explore the potential use of the social media as well as the release of a newsletter.

## 5.1 PROJECT LOGO

From the very early stages, a project logo was created to identify the project. It was used for the first time during the kick-off meeting of the project. There were different options and a round of voting took place in the Consortium, before the kick-off meeting of the project.

Comments received from all contributors were considered to improve and finalize the DocTIS logo. The figure below shows the final version selected and the improvements implemented to finalize it.



Figure 1 Final logo

## 5.2 PROJECT WEBSITE

Significant efforts have been devoted to the set up the project webpage, launched in May 2020, as a critical tool for external and internal communication of the project both by the Consortium and the European Commission.

The project URL is: <https://www.doctis.eu>.

The look and feel of the website have been designed taking into account the type of content to be communicated and the colour palette of the final logo of the project. The main goal is to have a simple, flexible display that can be equally accessible when using different resolutions and devices (computers, smartphones, tablets, etc). Content and pictures were selected considering the different target audiences and the main keywords related to the project.

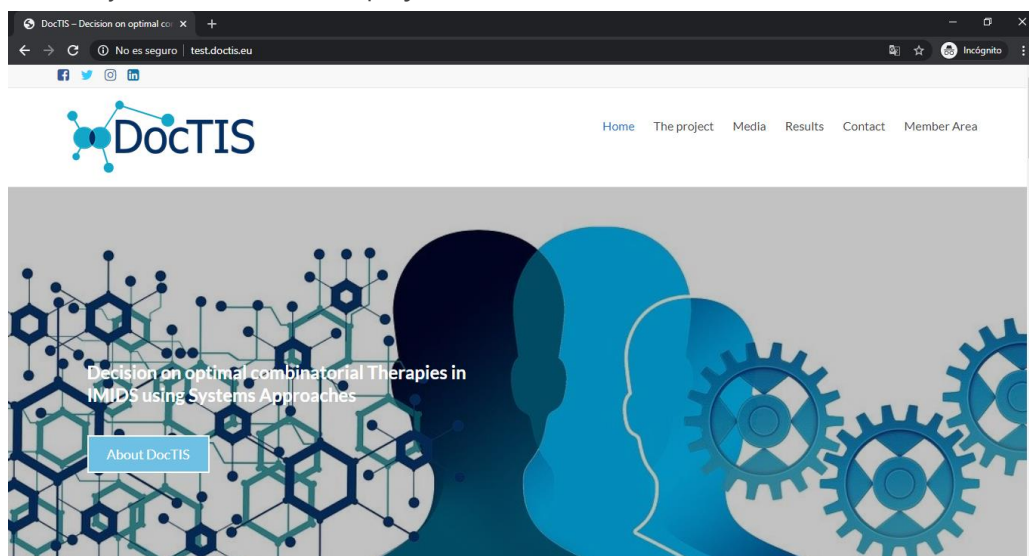


Figure 2 Website



## 6. COMMUNICATION STRATEGY

As mentioned in previous sections, the communication strategy of DOCTIS is determined by the nature of the project, develop new concepts on combinatorial therapies and treatment personalization. Effective communications using timely and clear messages to key stakeholders are essential to avoid confusion and efficiently manage expectations.

Some preliminary key messages have already been developed for the website launch, and the press release and the factsheet development. Such messages are depicted in the following table:

Table 1. DOCTIS key messages

The European project DOCTIS aims to provide a clinical proof of concept that, by gaining a systems-level knowledge of the pathophysiology of the immune system in immune-mediated inflammatory diseases (IMIDs), a precise prediction on the optimal combinatorial therapy for a given patient can be achieved.

DOCTIS is investigating the development of a personalised cost-effective combinatorial therapy response biomarker with a sensitivity and specificity of at least 80%.

The final objective of the project is to generate knowledge for development combinatorial therapies that will be tested in a pre-clinical stage in an exploratory clinical trial.

How systems level analysis of clinical and molecular data using the learning disease models framework could help to develop new therapies.

The socio-economic and psycho-social impact of the development of new combinatorial therapies.

Background: nowadays, there are up to 44 million IMID patients in Europe who can benefit from the synergic effect of combinatorial therapies.

While the preparation of dissemination materials and communication messages are required from the project onset, it is to be considered that objectives and activities in the Communication Plan may change as the project evolves and results are made progressively available. Accordingly, the DOCTIS general strategy has been envisaged in three different non-consecutive phases.

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### **Phase 1: Build awareness and communicate the importance of combinatorial therapy**

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The priority of this phase is to present the project in order to build awareness (communication objective 1) about the project, whilst research work is focused on the research activities. Therefore, during this phase special emphasis is given to the development of the communication tools and general presentations to the targeted audiences. This phase will run from year 1 to year 5 of the project.

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### **Phase 2: Engage stakeholders**

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Once the initial phases of the project have been completed, it will be time for engaging other stakeholders and initiatives (communication objective 2), liaising with policymakers and authorities more

intensively, and releasing major achievements of the project in a targeted way to continue to raise awareness about the project's results. This phase will run from year 2 to year 5 of the project.

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### Phase 3: Exploitation of the new combinatorial therapy

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Due to the nature of the project, the potential exploitation of the combinatorial therapy becomes a critical aspect. This phase will take into account exploitation aspects, such as the devise of specific proposals for implementation, and the promotion of the combinatorial therapy by the identified target users (communication objective 3). This phase will run from year 3 to the end of the project.

The following table outlines the phases of the communication strategy:

Table 2. DOCTIS communication strategy

<i>Objective</i>	<i>Audiences</i>	<i>Actions</i>	<i>Tools</i>
Commitment of the key stakeholders	Patient organisations, citizens	General scientific papers	
Awareness of the project among a wide defined group of audiences	Clinicians Scientific Community	Presentations at congresses and conferences	
Engage policy and decision makers	Scientific Societies	Mass and specialised media	Logo Website Press Releases
Awareness	Regulatory Authorities and Policy makers		PowerPoint Presentation
Ensure usage	Volunteers of the trial Pharmaceutical Industry	Information in the hospitals	Factsheet Posters
	Other related projects and initiatives	Concertation activities	
		Specific scientific papers	
		Individual meetings	

Each phase above includes the objectives, audiences, actions and tools foreseen. These components will be obviously combined in a logical way to fulfil the ultimate communication needs (e.g. to raise awareness among patients, in phase 1 press releases will be used through media; in phase 2, meetings and information in the hospitals will be the preferred action, and PowerPoint presentations and fact sheets will be the tool of choice).

## **7. EVALUATION OF THE RESULTS**

Measuring the success of communication is important, not only because the Communication Plan needs to be adjusted in light of the results obtained and the need to reformulate the overall strategy in response of the progress of the project.

The quantitative indicators indicated below will help the Consortium evaluate the communication in terms of visibility and awareness of the project:

1. Average number of visits on the website
2. Number of articles/appearances (press coverage) in media.
3. Number of Scientific publications/ communications.
4. Number of oral and poster presentations in national and international conferences.
5. Number of flyers/brochures distributed.

In order to assess indicator 1, an online facility for obtaining traffic analysis of the website will be installed. Google™ Analytics is a free service offered by Google™ that generates detailed statistics and allows tracking visitors from all referrers, including search engines, display advertising, pay-per-click networks, email marketing and even digital collateral such as links within PDF documents.

With regards to indicators 2 to 5, partner VHIR, as the leader of the Dissemination and Exploitation Work Package, is responsible of tracking the project's dissemination activities, maintaining a registry of documents related to each activity (e.g. digital and hard copy, brochures of events, etc.). For this purpose, a spreadsheet (see Annex F - DocTIS Dissemination Activities Spreadsheet) has been created to keep track and help partners report all their dissemination activities (planned and carried out). DocTIS partners are asked regularly to check the list of reported dissemination activities and update/correct the information contained therein.

## **8. COMMUNICATION CRISIS**

As mentioned previously, the main objective of this plan is to prevent a crisis. In the case such a crisis could not be avoided, the objective will be to minimize its impact on the project and in the members of the Consortium.

In order to achieve this objective, a series of sequential problem-managing steps have been established in DocTIS:

- Define the potential crisis situation.
- Assess precedent situations (e.g. in other previous projects) that are similar to the one identified as potential crisis.
- Prepare a project portfolio with general publishable information to be distributed.
- Prepare a unique message in response to the potential crisis that will be shared and used by the Consortium partners.
- Prepare in advance potential questions and answers related to the crisis situation.

- Have a list of identified journalists or stakeholders with influence on the public opinion and that can be addressed if required.
- Revise and regularly update the list of potential crisis situations.
- Document the crisis and its resolution during the project life span.

The Steering Committee will act as a **Crisis Committee**. According to the nature of the particular crisis, additional Consortium members with the specific expertise will also be called to join the Crisis Committee. The Crisis Committee will have a unique spokesperson that will be the DoCTIS Project Coordinator. Only in the case that the spokesperson is not capable to cope with the actions required to represent the Consortium, additional members of the Crisis Consortium will be required to assist him/her.

## 9. COMMUNICATION BUDGET

DoCTIS is a research project and, as such, most of the funding received from the European Commission is devoted to research activities. However, given the increasing importance in research of a good communication strategy (and more so in the case of projects dealing with sensitive health topics like DoCTIS), the Consortium has made a provision of funds for the development of communication tools and the implementation of dissemination activities as foreseen in the Communication Plan.

All partners in DoCTIS are expected to contribute to the dissemination of the project from its onset, and a minimum personnel budget has been allocated for each one of them. VHIR, as leader of the Dissemination and exploitation Work Package, and as coordinator of the DoCTIS project, has received a slightly higher amount for this objective, due to the bigger dedication expected from its end.