



Project full title:

Hepatic and Cardiac Toxicity Systems modelling

Project acronym:

HeCaTos

Collaborative project

HEALTH.2013.1.3.-1:

Modelling toxic response in case studies for predictive human safety assessment

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Deliverable Report D13.3:

Development of Dissemination and Communication Plan of the HeCaTos project

Work package 13

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PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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EXECUTIVE SUMMARY

The purpose of this Deliverable 13.3 is to outline the Training and Dissemination plan for the HeCaToS project; it will define the objectives, target audience, dissemination tools, planned training events and dissemination results to date.

Developing an effective dissemination strategy is essential in order to make sure that the HeCaToS research results reach our target audience, academic community, industrial and regulatory stakeholders and policy makers. Within the context of this report dissemination and training can be internal to the HeCaToS consortium but will mainly be to the project stakeholders and the target audience.

All consortium partners have a commitment to disseminating the outputs of the project. The projects own dissemination will primarily be through the project website, scientific articles, social media and HeCaToS training Courses and Workshops. The consortium partners will be asked for a dissemination update every month or 2 and the dissemination plan will be continuously updated. There will be a formal review of the dissemination plan every 12 months at the Annual Meeting after which the dissemination plan will be re-issued to consortium members.

There are two distinct factors in the dissemination strategy; project visibility and dissemination of results. Name recognition will dominate early on in the project and results will come to dominate the dissemination strategy towards the end of the project. However, both factors will always be present at a certain level.

OBJECTIVE

The overall objective is to identify and reach stakeholders, including end users and the public, in order to raise their awareness regarding the findings of the consortium. More specifically, the sub-objectives include the following:

- Elaborate the consortium's strategy for dissemination activities and engaging stakeholders;
- Identify and engage stakeholders throughout the course of the project in order to ensure that the results of the project are applicable and appropriate to stakeholders;
- Establish and maintain the project's website;
- Prepare and translate press releases and other materials for dissemination to the media and other stakeholders as many Member States as possible;
- Prepare scientific journal articles and conference presentations.

The objective outlined above will ensure that the HeCaToS project will fulfil the EU FP7 Grant Agreement requirement to communicate and engage with actors beyond the research community.

PROJECT OVERVIEW

HeCaToS aims at developing integrative in silico tools for predicting human liver and heart toxicity. The objective is to develop an integrated modeling framework, by combining advances in computational chemistry and systems toxicology, for modelling toxic perturbations in liver and heart across multiple scales. This framework will include vertical integrations of representations from drug(metabolite)-target interactions, through macromolecules/proteins, to (sub-)cellular functionalities and organ physiologies, and even the human whole-body level. In view of the importance of mitochondrial deregulations and of immunological dysfunctions associated with hepatic and cardiac drug-induced injuries, focus will be on these particular Adverse Outcome Pathways. Models will be populated with data from innovative in vitro 3D liver and heart assays challenged with prototypical hepato- or cardiotoxicants; data will be generated by advanced molecular and functional analytical techniques retrieving information on key (sub-)cellular toxic events. For validating perturbed AOPs in vitro in appropriate human investigations, case studies on patients with liver injuries or cardiomyopathies due to adverse drug effects, will be developed, and biopsies will be subjected to similar analyses. Existing ChEMBL and diXa data infrastructures will be advanced for data gathering, storing and integrated statistical analysis.

Model performance in toxicity prediction will be assessed by comparing in silico predictions with experimental results across a multitude of read-out parameters, which in turn will suggest additional experiments for further validating predictions. HeCaToS, organized as a private-public partnership, will generate major socioeconomic impact because it will develop better chemical safety tests leading to safer drugs, but also industrial chemicals, and cosmetics, thereby improving patient and consumer health, and sustaining EU's industrial competitiveness.

1. DISSEMINATION STRATEGY

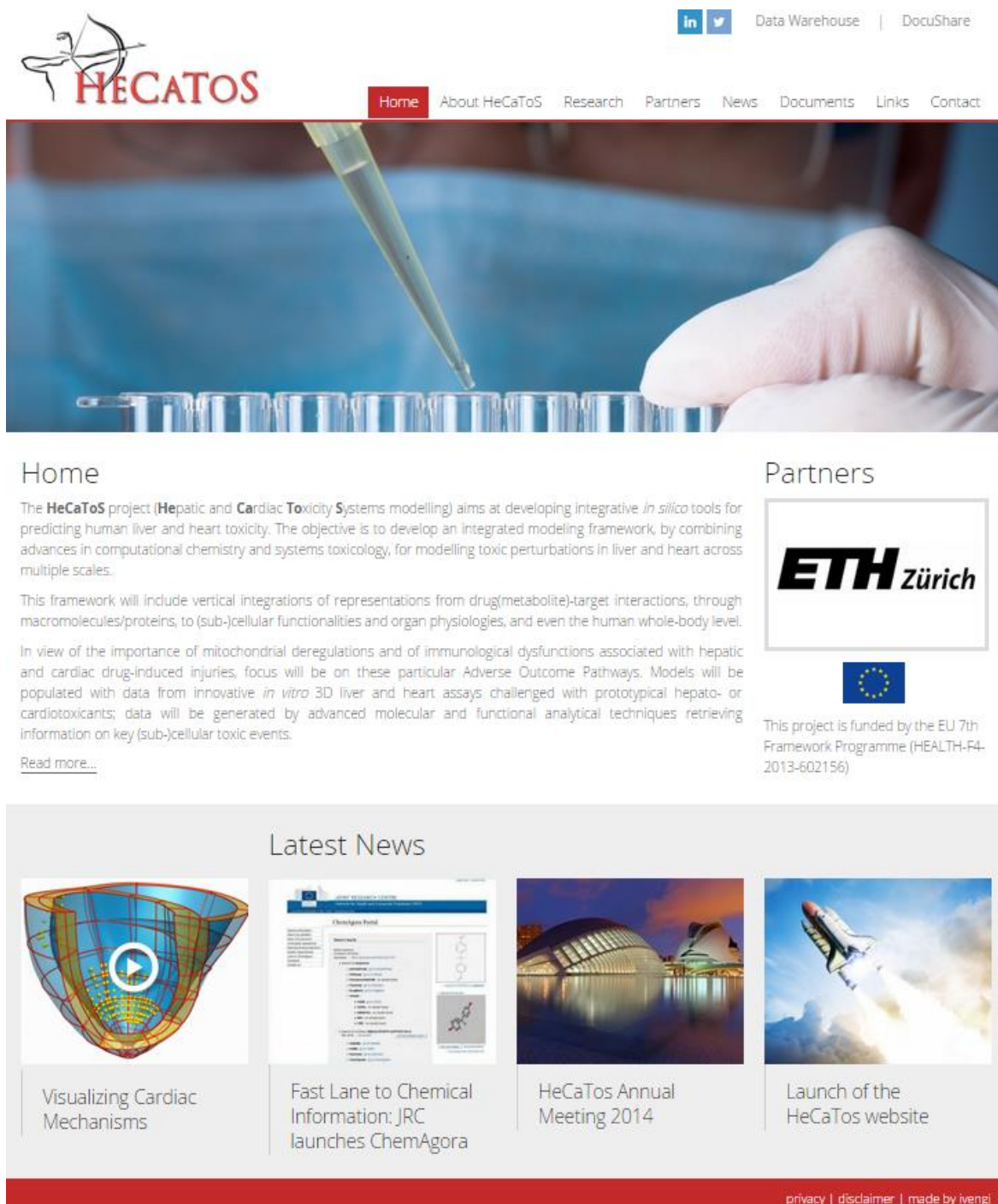
Developing an effective dissemination strategy is essential in order to make sure that the research results and data resources reach our target audience. The HeCaToS dissemination strategy covers both internal and external communication and dissemination. The project website has both internal and external audiences in mind. There are two distinct factors in the dissemination strategy; project visibility and dissemination of results. Naturally project visibility will dominate early on in the project and the dissemination of results will come to dominate the dissemination strategy towards the end of the project. However, both factors will always be present at a certain level.

All project partners have a commitment to dissemination and all engage in their own dissemination activities, ranging from peer-reviewed publications, presentations at scientific conferences to institute open days. All partners are encouraged to disseminate the project url (www.hecatos.eu) through their email signature. Imperial College London (ICL9-WP13) will function as coordinator for the dissemination activities and develop the dissemination plan. The dissemination plan is geared not only to organise but also to collect, distribute further and provide an overview of the project dissemination efforts.

The dissemination plan will be continuously updated; a formal review will take place every year at the HeCaToS board meeting. Partners in the consortium are asked and encouraged to submit regular updates of their dissemination activities; a reminder will be sent every 2 months to ensure the dissemination plan is kept up to date.

1.1. Establish and maintain the project's website

Partner UM had the project website (www.HeCaToS.eu) up and running 3 months after the HeCaToS kick-off meeting. The website will be the main point of reference for external communication. Specific details relating to the website can be found in the report "D13.2 Report on status of the launch of the HeCaToS website". The project website is the primary place for stakeholders to find information about the HeCaToS project as well as providing access to DocuShare®, the internal website for the consortium partners. All public results will be made available through the project website.



The public webpage will allow sharing scientific knowledge. It presents the project and its aims, the project organization, the participants, and, in suitable cases, the methods developed by the project. Background information such as relevant regulations and directives as well as intentions and policies of different organisations will also be presented. Moreover, the communication system will have links to the websites of other relevant EU projects, with previous agreement with the consortia Coordinators. This would encourage cooperation between existing projects and would avoid unnecessary duplication of efforts. The public webpage will be the basis for the dissemination of the project results including harmonized protocols of developed systems models and standard operation procedures in bioinformatics/biostatistics, as well novel tools and techniques for data analyses. In addition, the public webpage will include workshop and meeting reports, and training possibilities offered by the consortium. As soon as the publications will be accepted, they will be made available on the public webpage in electronic form.

In order to inform the general public, the public website will also present project objectives, approaches and methods, as well as the outcome of the scientific work, in layman's language. This will also service to provide greater visibility and awareness of EU investments in health research, thereby generating a positive understanding of the use of European funds and to obtain public support for the need for such programmes and projects.

1.2. Prepare and translate press releases and selected other materials for dissemination to the media and other stakeholders as many Member States as possible

In addition to disseminating project results to interested and relevant stakeholders, HeCaToS also seeks to engage a diverse array of stakeholders from all different categories, including policy makers, public authority representatives, the media, industry, system operators, civil society organisations and citizens, throughout the project. In order to do so, we will use the project deliverables, the research reports and case studies, as a basis for discussion with a broad range of stakeholders electronically, in interviews and face-to-face in workshops, the outcomes of which are also expected to contribute to the consortium's research and analyses. The dissemination strategy will enable stakeholders to provide feedback on the project's deliverables, which will feed into the project at its various stages.

Effective dissemination results in the establishment of contacts and interconnection of networks - a legacy that often outlives the project. The HeCaToS dissemination strategy therefore aims to identify and establish contacts with other relevant projects and studies, to increase awareness of the consortium's work and the HeCaToS research results. A further objective of the strategy is to facilitate collaboration among different groups of stakeholders to enhance uptake of the project's results and integration of different and diverse end-user knowledge.

The consortium will place particular emphasis on facilitating this collaboration, establishing important links and closely integrating with other organisations carrying out similar or related research and analysis. This integration and collaboration effort will not only strengthen the research and knowledge base for the research activities carried out in HeCaToS, but also open up possibilities of enhancing future cooperation. It is important to distinguish between groups of stakeholders, and their different interests, across countries, disciplines and institution type.

1.3. Prepare scientific journal articles and conference presentations

Members of the HeCaToS consortium will prepare articles and presentations for academic audiences, across a range of disciplines, as the issue affects all fields of research. Conference presentations are an opportunity to interact with academic stakeholders, and to receive feedback on our results.

1.4. Audience

The HeCaToS project has as a target audience the toxicology and toxicogenomics research fields, academic community, industry, regulatory bodies, and policy makers. To better define the target audience, a stakeholder analysis was carried out to identify organisations and individuals who will have bearing on the HeCaToS project.

The HeCaToS project will work with a range of dissemination tools to reach the different classes of target audience. Material tailored to different dissemination activities will be developed during the project.

Dissemination and stakeholder engagement is central to the success of HeCaToS. This document provides a description of the HeCaToS dissemination strategy. The HeCaToS consortium recognises that dissemination activities are an essential and pervasive activity throughout the project's life, and integrated within all its work packages.

1.5. Stakeholders

Since demands for better chemical safety tests have strongly increased over past years, the outcome of this project will generate considerable socio-economic impact. All in all, EU's society and economy require reliable chemical tests which better predict risks to consumers' and patients' health and also come cheaper than current animal tests. The foreseen outcome of the work under HeCaToS will thus have a significant impact on public health, health-care costs, and competitiveness of European pharmaceuticals, cosmetics and chemical industry and biotech companies, by:

- Enabling to reliably determine potential longer-term, repeated dose adverse health effects of chemical entities, by developing organ-specific *in silico* models based on human cell and organ systems, thereby avoiding 'false positive' or 'false negative' reporting due to unforeseen inter-species differences in toxicity mechanisms.
- Enabling to determine toxicity risks much earlier and quicker in the development processes than through current *in vitro* and *in vivo* testing approaches, thereby shortening time needed for adequate safety assessments of novel chemical entities

At the end of the HeCaToS project, in anticipation of regulatory needs, computational prediction models for chemical safety as generated by HeCaToS, will be proposed to the European Centre for the Validation of Alternative Methods (ECVAM) for considering these systems models for pre-validation and subsequent formal validation. This will support the progression towards the acceptance of these predictive models by EU regulators.

This project will be able to endorse the societal acceptance of these computational models for chemical safety assessment also by the fact that its advisors will be attracted from EU regulatory authorities such as EMEA, ECHA, SCCS and EFSA.

Acceptance of the outcome of the work under HeCaToS by end-users from industry will increase the likelihood of effectively implementing model-based prediction tools as to be developed by this project, already at an early stage of product development, and this will be stimulated by the fact that Roche and Bayer (indirectly) as potential end-users are partner in this consortium. The foreseen collaboration of academic researchers with LE and SME partners will guarantee that adequately validated proof-of-principle will be delivered, while offered technological solutions to problems raised by current test batteries for assessing chemical safety, will be fit-for-purpose, thus leveraging the ultimate acceptance of developed *in silico* models by industrial users.

Assuming that our computational prediction models for human liver and heart toxicity will be scientifically valid and that they therefore will be accepted by the scientific community, their further acceptance is dependent on important stakeholders becoming convinced of their relevance and reliability. We assume that for this, their biological, technical and formal validation is crucial. While the legal and institutional organizational environment in regard to worldwide regulations on human safety assessment involves multiple regulatory stakeholders, the regulatory and legislative background of predictive toxicity tests being governed by worldwide agreements, consensus entities and international institutions such as EMEA and the OECD, we assume that industrial stakeholders play a major role, considering that early acceptance of particular safety tests and subsequent use during early stages of product development may stimulate their ultimate acceptance by these regulatory authorities. We also assume that achieving the foreseen impact of this project will be facilitated by the fact that SMEs as important technology providers and LEs representing big pharma, are participating in this project.

Stakeholder engagement is key to the success of any initiative. One of the principal tasks of HeCaToS is to define and agree upon stakeholder categories that will provide an initial point of reference for the dissemination strategy. However, these categories may be updated and redefined as the project progresses.

Therefor WP13 will publish an electronic newsletter and factsheet that both will be distributed to interested and relevant partners, organizations and key stakeholders (from industry, academia and regulatory agencies) every year focussing on presenting results from the HeCaToS project.

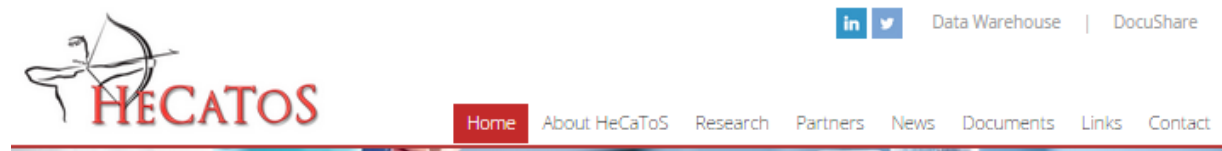
1.6. Internet-based Communication

1.6.1. Intranet

To ensure optimal cooperation within the HeCaToS consortium, exchange of information and standardization, a secure internet-based communication system Docushare[®] has been set up. This communication system is for internal use only, i.e. only consortium partners and members of the Scientific Advisory Board of the HeCaToS project have access to it.

1.6.2. Social media

The HeCaToS project has active participation in social media as these are potentially useful dissemination tools and channels. A HeCaToS twitter account (https://twitter.com/HeCaToS_FP7) and LinkedIn group (<http://www.linkedin.com/groups?home=&gid=4319738>) has been created to ensure a presence in the social media. The Twitter/LinkedIn account will be used to alert followers to updates on the website, upcoming training events and to disseminate results. The social media presence is managed by UM and ICL.



We have decided not to use Facebook, given the long lead time to establish an effective Facebook group.

1.7. Publications

Publications are an important and broad-based tool to disseminate the knowledge developed during the lifetime of the project. We expect peer-reviewed journal articles to be published in the course of the HeCaToS projects. These will ensure that RECODE has a long-lasting impact beyond the project duration, particularly in relation to academic discourse in the area. Besides publications in peer-reviewed journals we anticipate publications in blogs, magazines and newsletters of interest.

Press releases will be issued when it is felt to be appropriate by the project coordinator and the Dissemination Officer. The timing will be determined by the need to communicate a specific message rather than *a priori* fix on a number of press releases or establish times at which they will be issued. A press release was issued at the start of the project (<http://www.HeCaToS-fp7.eu/news/press-release-start-HeCaToS>) and we would anticipate as well as at the end of the project.

1.8. Conferences & Meetings

Conferences are a means of developing national and international connections with governmental, advocacy or academic opinion leaders, and engaging in a direct, face-to-face communications and discourse. Members of the HeCaToS consortium will be presenting talks/posters at national and international conferences. A list of presentation and posters will be made available on the HeCaToS project website. The pdf of the presentation/poster will be placed on the website unless releasing this information publically is considered to prejudice subsequent publication of novel results.

The HeCaTos consortium will organize at the end of the project a final conference. The conference represents an important channel for the dissemination of HeCaTos results to stakeholders, policymakers and the public. Its main aim will be to provide an overview of results of the HeCaTos project, with a special focus on the policy implications, to raise public awareness on the research field covered by HeCaTos, to bring interested parties at different levels closer to EU research, to account for how public money was spent and to foster research in the European Research Area. The Final Conference will also provide the opportunity to share preliminary ideas on research gaps that remain unfilled as a follow-up to HeCaTos research activities. Due to its early stage we are not able to provide detailed information on this topic.

1.9. HeCaToS Training workshops

The HeCaToS training workshops are a key part of the project Dissemination Plan and will act as a multiplier since workshop participants will subsequently share information about the project with other stakeholders. A series of Workshops are foreseen during the life-span of the project (WP13).

1.10. Dissemination Timetable

The following illustrates the dissemination activities of the HeCaToS project based upon a month-by-month delivery schedule. The scheduling of these activities is closely aligned with key project deliverables. Some activities (e.g. e-mail and press releases) intensify pre and post key deliverables. These time frames should be regarded as indicative.



HeCaToS -Hepatic and Cardiac Toxicity Systems modelling



Type of activities	Main Leader	Title of event	Date	Place	Type of audience	Size of Audience	Countries addressed
2013							
Media briefings	Maastricht University	Safer and more effective testing of chemicals without lab animals	2 Oct. 2013	Maastricht, the Netherlands	Medias	Unknown	European Union
Publications	MPIMG	Lienhard, M., Grimm, C., Morkel, M., Herwig, R., Chavez, L. MEDIPS: genome wide differential analysis of sequencing data derived from DNA enrichment experiments. Bioinformatics, 30:284-286.	13-11-2013	Berlin	Research	>10000	Worldwide
Conference	MPIMG	Talk (R. Herwig): "Predictive network modelling of toxicogenomics data". 11th International Conference on Environmental Mutagens	4-11-2013	Foz do Iguassu, Brazil	Scientific community	>1000	Worldwide

2. CONCLUSION

This dissemination strategy provides the HeCaToS project with a solid framework against which to begin disseminating project results and activities.

The HeCaToS consortium will use this as an initial strategy which will be further reviewed, revised and updated as dissemination materials and specific strategies are evaluated for their reach, effectiveness in targeting particular stakeholders and alignment with stakeholder interests and barriers. This document, and more importantly the dissemination strategy, will be revisited frequently in light of experience.