Grant Agreement no. 634413

EPoS

Elucidating Pathways of Steatohepatitis

INSTRUMENT: Research and Innovation Action

TOPIC: PHC-01-2014

D10.1: Detailed dissemination plan

Due Date of Deliverable: 31st August 2015
Completion Date of Deliverable: 2nd September 2015

Start date of project: 1st May 2015 Duration: 48 months

Lead partner for deliverable: iXscient

Revision: v1.0

Project co-funded by the European Commission within the Horizon 2020 Framework Programme (2014-2020)		
Dissemination Level		
PU	Public	✓
CO	Confidential, only for members of the consortium (including Commission Services)	

Document History

Issue Date	Version	Changes Made / Reason for this Issue
4th August 2015	v0.1	First draft
10th August 2015	v0.2	Additions from UNEW
28th August 2015	v0.3	Additions from all partners
2nd September 2015	v1.0	Final version

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1. Introduction

The technology development in EPoS associated with novel biomarkers, diagnostics and identification of therapeutic targets will provide a significant step forward in the state of the art and in clinical opportunities for improved patient identification, risk-stratification and management. The ability to understand how host and environmental factors interact at the cellular, organ and organism level to promote the development of NAFLD will lead to a significant improvement in the cost-effective diagnosis, prevention and treatment of this disease in European Health Systems.

To ensure these benefits, the consortium firmly intends to disseminate the results from the EPoS project to a very wide audience. With technology providers, clinical end users and a commercial biomarker development company all involved in the project, the diversity regarding where the project information can be publicised is extensive. It is essential that the general public are made aware of the new medical technologies being developed in a broader "publicity type" approach, while the clinical teams and possible commercial exploiters of the technology will both need a more technical workshop and training type approach. To that end, accompanying the scientific and technological outputs planned for EPoS, there needs to be a forum to facilitate informed public, industry and government debate about any issues raised by the impact of discoveries by EPoS.

The principle aim of this activity is therefore to disseminate research results to the public and relevant actors in the field, and to promote awareness and acceptance of the EPoS technology and its benefits. However, within the project, dissemination activities will always be tempered by the requirements to safeguard intellectual property as this will have a significant impact on the exploitation of the project results and commercial viability of any resulting product. The dissemination element of the project is also important for its role in preparing the marketplace and favourable conditions for making broad use of the EPoS knowledge and European NAFLD Registry.

The EPoS dissemination strategy is based on the objectives of the project, the stakeholders within the consortium and the requirement to significantly impact the market. The advances throughout the project need to be disseminated to the scientific community while the benefits of the innovation need to be promoted to the general public and end users as well as potential collaborators for future development and clinical uptake. In deciding on a dissemination strategy for EPoS, all these factors have been taken into account. As a result, the dissemination strategy comprises a matrix of three distinct groupings:

1. Dissemination methodologies targeted at the specific audiences (scientific, clinical, academic, patient groups and the general public).
2. Promotion through various public sector health associations/agencies, focusing in particular on liver disease.
3. Networking with user groups, conference and trade show organisers, etc.

To enact this strategy, EPoS is engaging the stakeholders in a variety of ways including:

- Conferences and workshops targeted at specific stakeholder groups.
- Scientific publications.
- General publications targeted at specific stakeholder groups.
- Participation in relevant EU activities (e.g. concertation meetings, interaction with other European projects, etc.).
- "Open house" activities/demos to present the project outcomes to specific audiences (e.g. specialized industries, user groups, public health agencies).

- Integration of the main scientific results and methodologies in the advanced graduate courses/seminars taught at the universities of the academic partners. In addition, there will be opportunities for research projects/graduate theses for the students in these universities on topics related to the proposed research.
- Dissemination through other relevant Research Projects belonging to National Excellence Programs, where there are interesting synergies.
- Project website.
- Flyers and other project literature.

From its dissemination activities, EPoS seeks to develop a distinctive "corporate" image, including a logo and presentation templates, which are easily identifiable by all the interested stakeholders. The particular nature of the project and its natural evolution shall be reflected in this strategy and changes to some of the activities set out in this document may be necessary during the lifetime of the project. The project will endeavour to be both effective and efficient in its dissemination activities. This will involve an on-going review of the methods employed and changes and updates as necessary.

2. Dissemination Strategy

To set the scene for the EPoS dissemination strategy, it is important to understand the project objectives and some of the issues facing the healthcare industry and potential impact on the community.

Non-alcoholic fatty liver disease (NAFLD) represents a spectrum from isolated hepatic triglyceride accumulation (steatosis); through hepatic triglyceride accumulation plus inflammation (non-alcoholic steatohepatitis, NASH); and ultimately progressing to fibrosis/cirrhosis and potentially hepatocellular carcinoma in the absence of excessive alcohol consumption.

With the advent of increasingly sedentary lifestyles and changing dietary patterns, NAFLD prevalence has increased dramatically in concert with the rapidly progressing epidemics of both adult and childhood obesity and type 2 diabetes mellitus. NAFLD has therefore become one of the top concerns for practising hepato-gastroenterologists and endocrinologists due to its potential to progress to advanced liver disease and metabolic complications. Importantly, there is a growing body of clinical and epidemiological evidence suggesting that NAFLD leads to not only liver-related mortality but also worsening insulin resistance and increased risk of ischaemic heart disease and stroke. The problem of healthcare provision for liver disease in general, and NAFLD in particular, is thus a global challenge for the future years.

NAFLD is characterized by substantial inter-patient variability in terms of severity and rate of progression: although a large proportion of the population is at risk, only a minority experience associated morbidity. Epidemiological evidence indicates that patients with NASH are at significantly greater risk than those with simple steatosis. However, what determines the progression to NASH and beyond is not clear and these groups can currently only be differentiated by liver biopsy, a costly and potentially risky invasive procedure.

The key challenges of EPoS are to understand the biological and environmental factors that drive inter-patient variability within the NAFLD spectrum and to use this understanding to develop robust methods for diagnosis, risk stratification and therapy so that effective medical care may be targeted to those at greatest risk.

While it is very important to disseminate the results of the project as widely as possible, consideration must also be given to any confidential information, the public dissemination of which could impact any future patent applications. Therefore, all dissemination will follow the

publication clearance procedure specified in the Consortium Agreement and in the Project Handbook.

Basic research will be disseminated through the normal scientific and academic route of peer reviewed publications. It is also expected that the project will promote itself through journals, conferences, trade magazines, trade shows and networking events. Aspects of these are discussed later in the document.

Dissemination to the general public is multifaceted. This comprises raising the general awareness of the worldwide health issues, the progress being made in the project and the potential of the technology for everyone. To achieve this, a number of dissemination routes have been identified:

- EPoS website
- Project flyer
- Multilingual press releases
- Attendance at international conferences
- General press coverage – TV, radio, national and local press

The attainment of the dissemination strategy can be achieved through the establishment of links with distinct but overlapping target groups and end users, such as trade associations, patient support groups, policy makers, healthcare providers, industrial and research entities. The methods through which EPoS can reach these target groups involves varying approaches that can be grouped as either clustering activities with other on-going actions/projects, or through conference activities, either at periodic venues or specific EPoS-organised and sponsored events.

Within the EPoS consortium, there are five clinically oriented academic institutions (UNEW, UCAM, UHEL, UNITO and UMC), three research institutions (ICAN, CNR, SDC) and one commercial biomarker development company (NB). Some of the academic partners are also linked to medical centres. Many dissemination activities targeted at industry and healthcare providers will be co-ordinated through all these partners, with input from the other partners as necessary.

Key to the successful exploitation of the discoveries will be our links with a network of industry partners that EPoS has assembled (the 'EPoS Network'). This includes some of the world's largest international pharmaceutical companies (e.g. GlaxoSmithKline and Boehringer-Ingelheim) as well as a number of smaller companies that have invested heavily in drug development in this field and have promising lead compounds in phase 2 trials worldwide (Intercept and Genfit). Several of the EPoS collaborators already have mature collaborative links with these organisations (Boehringer-Ingelheim: UMC; GlaxoSmithKline: UNEW; Intercept: ICAN and UNEW; Genfit: ICAN). Thus, EPoS is well placed to discover and innovate, validate the results of our discovery science in our highly phenotyped cohorts, and to exploit our findings by bringing them to the clinic for the benefit patients with NAFLD.

The research infrastructure developed during EPoS will also be exploited. The EPoS database and biobanks will form the nucleus of an on-going European Collaborative Research Network on NAFLD that will remain after the funded period of the EPoS programme has passed as a central collaborative resource to support European investigators across Europe.

During the first 18 months of EPoS, a set of promising end-users will be identified and contacted in order to evaluate and understand their potential interest and capability for collaborating with the project. The process will be organized as shown in the following table:

End-User Name or Type	Country	Domain	Type of action performed by EPoS
European Association for the Study of the Liver (EASL)	Europe	Dissemination Possible joint workshop	Consider presentation at annual EASL Meeting
NAFLD study group of the European Association for the Study of Diabetes (EASD)	Europe	Dissemination Possible joint workshop	Contact through various EPoS partners who are members Consider presentation at annual EASD Meeting
GlaxoSmithKline	Europe	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Boehringer-Ingelheim	Europe	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Intercept Pharmaceuticals	USA	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Genfit	France	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Novo Nordisk	Denmark	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Novartis	EU-USA	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Astra Zeneca	UK, USA	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Mitsubishi-Tanabe	USA-Japan	Exploitation	Contact through EPoS Network, invite to EPoS workshops
Conatus	USA	Exploitation	Contact through EPoS Network, invite to EPoS workshops
External members of EPoS Exploitation & Impact Sub-Committee	Portugal, Switzerland	Dissemination	Present results and discuss knowledge transfer, obtain feedback on commercial opportunities

A number of deliverables will be publicly disseminated, and these will be made available on the project website (see below). Furthermore, public abstracts of all the confidential deliverables will also be produced.

2.1. Exploitation and Impact Sub-committee (EIS)

An Exploitation and Impact Sub-committee (EIS) will be setup to monitor these aspects, comprised of a relevant subset of partners. Two external experts will also be appointed to this sub-committee. The EIS will review key performance indicators and give feedback on the commercial and impact success of the project. It will provide reports to the Steering Committee at least annually. Its remit will cover:

- Commercialisation
- Standards
- Management and protection of Intellectual Property
- Dissemination
- Identification of exploitable project results
- Market analysis
- Identification of business opportunities

Further details of exploitation activities will be provided in an Exploitation Plan to be produced at month 12 and regularly updated throughout the project. For now, it is sufficient to note that, as part of exploitation, there may be some dissemination to other companies who may ultimately be interested in using or licensing the technology.

3. Dissemination Methodologies

3.1. Journals / Conferences

Raising awareness of the EPoS project and its results to relevant stakeholders is an important feature of the project. The strong multidisciplinary character in EPoS provides a wealth of channels for distribution of relevant information.

Partners have been successful in the past in publishing in top journals and conferences in their areas of research, and it is expected that the same will happen in the context of this work. The EPoS project will produce a significant number of publications, given the substantial research effort within the area of NAFLD diagnosis, prevention and treatment. Our findings will be disseminated in international conferences and area-specific workshops including major organisations such as EASL (European Association for the Study of the Liver), AASLD (American Association for the Study of the Liver) and EASD (European Association for the Study of Diabetes), AGA (American Gastroenterological Association), UEG (United European Gastroenterology) and ADA (American Diabetes Association). Dissemination at conferences will always go hand in hand with looking at competing research activities, which will be assessed to continuously update and fine-tune the EPoS roadmap. Conference sessions will be proposed at European international conferences such as EASL and EASD, as well as those held by national organisations including BASL, AFEF, AISF, GASL, etc. to disseminate the discoveries made during EPoS.

The majority of the conferences mentioned above are extremely competitive and generally have low acceptance rates. Technical papers that are accepted for publication to conferences are accompanied by a technical presentation outlining the core of the proposed solution, the improvement over the state-of-the-art, and a solid evaluation, demonstrating the validity of the proposed ideas and technologies.

Papers in each field will be submitted with frequency to renowned scientific journals such as: Gastroenterology, Hepatology, Journal of Hepatology, Diabetologia, Diabetes and Diabetes Care, Liver Transplantation, Analytical Chemistry, etc. with relevant discovery journals such as Nature Genetics, Nature Medicine, Nature Communications, NEJM and Lancet also considered when appropriate. Partners will use their involvement and status in the research community to impact major scientific events by organizing related panels, tutorials, and special sessions. In addition, seminars will be organized for business and healthcare managers. The consortium members have already indicated their interest, involvement, and determination to host, organize or participate in the external dissemination activities described above. All partners have an outstanding record of publications and impact on both the academic and clinical communities. Those partners with lecturing privileges will take advantage of their first-hand exposure to promptly include findings from EPoS in their course syllabuses.

3.2. Participation in program committees and editorial boards

Through such a position, EPoS participants will be able to play a role in setting the agenda and organising special sessions or special issues. Some examples of relevant affiliations are given below:

The liver group at Newcastle University (UNEW) is affiliated with the NIHR Biomedical Research Centre (BMRC) in Ageing that is jointly run by the Newcastle upon Tyne NHS

Hospitals Foundation Trust and UNEW. The BMRC is one of a small group of biomedical research centres of excellence funded by the UK Department of Health.

The Coordinator, Dr Quentin M. Anstee (UNEW), is an honorary group leader at the MRC Mammalian Genetics Unit, UK (MRC Harwell) and leads the MRC UK-GoLD (Genetics of Liver Disease) Consortium.

Dr Helen Reeves (UNEW) is currently a scientific committee member on the British Association for Cancer Research, as well as the UK representative on the Governing Board of the European Association for Study of the Liver (EASL).

Dr Dina Tiniakos (UNEW) is currently a Scientific Committee member of United European Gastroenterology (UEG) and an Executive Council member of the European Society of Pathology (ESP). She has recently been nominated President-elect of ESP. Dr Tiniakos is a member of the Editorial Board of the scientific journals "Liver International" and "Histopathology".

Prof Heather Cordell (UNEW) is Associate Editor for the journals Genetic Epidemiology (2011-present) and American Journal of Human Genetics (2014-present).

Prof Antonio Vidal-Puig is currently the Deputy Director of the MDU MRC Wellcome Trust Institute of Metabolic Science, Associate Faculty at Wellcome Trust Sanger Institute and Scientific Director of Cambridge Phenomics Centre at Cambridge University. Prof Vidal-Puig is currently a member of the Editorial Advisory Board: PLoS Biol (2009-) and Editorial Board Memberships: PLoS Biology (2007-), Diabetes (2012-) Trends Endocrinology and Metabolism (2008-), Biochim Biophys Acta.(2012-). Further board and committee memberships include:

- 2013- EASO Scientific Advisory Board
- 2013- Ageing Wellcome Trust Strategic Award Scientific Advisory Board
- 2012- IDIBAPS Scientific Advisory Board
- 2011- Severo Ochoa Research Excellence Awards Committee
- 2010- European Atherosclerosis Society, Scientific Committee
- 2010-2013 British Heart Foundation, Research Committee
- 2010- International Scientific Committee of CIBERDEM (http://www.ciberdem.org)
- 2010- FP7 FLORINASH Scientific Advisory Board (http://florinash.org/index.html)
- 2009- International Scientific Committee of CIBERObn (http://www.ciberobn.es/webciber)
- 2008- Diabetes UK, Research Committee

Prof Hannele Yki-Järvinen (UHEL) has chaired the Finnish Diabetes Research Society for the last 13 years.

Prof Elisabetta Bugianesi (UNITO) is currently an Associated Editor of Journal of Hepatology, where the possibility exists to suggest topics for special focus or review articles, which could include topics around EPoS. These would be subject to peer review in the usual way and do not create a conflict of interest.

Dr Amalia Gastaldelli (CNR) is the research director of the cardiometabolic risk group at the Institute of Clinical Physiology of CNR and an associate professor at University of Texas Health Science Centre (UTHSCSA) in San Antonio, Texas, USA. Dr Gastaldelli is also President of the NAFLD study group of the European Association for the Study of Diabetes (EASD), Director of the European Chapter of the American College of Nutrition (ECACN), member of board of directors of the American College of Nutrition (ACN) and member of the steering committee of

the EGIR group (European Group for the study of Insulin Resistance). She is also Associate Editor of the Journal of the American College of Nutrition.

Dr Matej Orešič is member of the Horizon 2020 Programme Advisory Group, Societal Challenge 1 "Health, demographic change and wellbeing". He has chaired the Personalised Medicine working group within the Advisory Group.

Dr Detlef Schuppan (UMC) is chair of the Institute of Translational Immunology, as part of the Research Center for Immunotherapy, at UMC Mainz. He is also Professor of Medicine at the Division of Gastroenterology at Beth Israel Deaconess Medical Center (BIDMC), Harvard Medical School in Boston, USA. The BIDMC has an expanding NASH-type 2 diabetes patient and research program with the Joslin Diabetes Center in Boston. Dr Schuppan is Associate Editor of the journals Gastroenterology and American Journal of Physiology (GI and liver). He has close connections with the Boston-Cambridge biotech community.

Dr. Jörn Schattenberg (UMC) is a research group leader and attending physician at the University Medical School Mainz. He is Member of the Editorial Board of the American Journal of Physiology - Gastrointestinal and Liver Physiology (AJP-GI) and leads the Scientific Abstract Committee for Liver disease for the German Association of Gastroenterologists (DGVS).

3.3. Workshops and Conferences

At least two open workshops/monothematic conferences will be held during the project to further disseminate current knowledge on NAFLD and the research undertaken by EPoS. These may be organised in conjunction with relevant conferences or meetings of liver associations (e.g. EASL). This will allow the assumptions and results achieved in EPoS to be challenged, which will provide useful feedback to the project. Moreover, it will open the path to novel co-operations that are of value to the consortium.

The first one-day workshop, co-organised with the Institute of Hepatology, will be held at the Academy of Medical Sciences, London, UK in Autumn 2015 and is entitled *"Frontiers in Hepatology: Non-Alcoholic Fatty Liver Disease & The Metabolic Syndrome"*. The programme will included state-of-the-art lectures from an international faculty including members of the EPoS consortium and a special lecture describing the role of EPoS as a catalyst for European collaborative research in the field.

3.4. Outreach Activities

Members of the EPoS consortium will also engage in outreach activities with local schools aimed at enthusing young scientists by experiencing real "academic" research. For example, Dr Fiona Oakley (UNEW) has for the past 5 years run research projects with local schools as part of "leading edge", a joint initiative between the Royal Society and Langton Star Centre. Students have the opportunity to visit a laboratory and participate in on-going research projects e.g. testing anti-fibrotic compounds in liver models, learning to be a liver pathologist and understanding how the liver becomes injured and regenerates. The pupils also research how social and lifestyle choices can cause liver disease including NAFLD. In addition to research project the pupils are trained in practical skills (workshop), poster making and presentation skills (theatre company). The research experience culminates with a conference style "grand finale" event where the students present their projects to peers, family and council members.

Publication information campaigns in Germany are planned by D. Schuppan and J. Schattenberg (UMC) as part of the National Liver Day which takes place in public areas (e.g. shopping malls).

3.5. Project Logo

Although not a dissemination mechanism in its own right, the logo of the EPoS project (shown below) is very important as it gives the project an identity. The logo is used on all EPoS documentation and at all dissemination events. The logo of the project was designed during the first months of the project. An animated version has also been produced for use on the project website and in PowerPoint presentations.

Figure 1: EPoS logo.

3.6. Project Flyer

A flyer will be designed, giving an overview of the project, its objectives, consortium partners, etc. This will be suitable for professional printing and used as handouts by the partners at various dissemination events. It will also be available for downloading from the project website.

3.7. Project Website

A project website will be produced (www.epos-nafld.eu) as a route to wider dissemination both to the general public and a medical professional/scientific audience.

3.8. Twitter Account

A Twitter account (@epos_nafld) has been set up for the project and a link added to the website. This will be used to highlight important events during the project. Partners are encouraged to follow the Twitter account from their own institution accounts.

3.9. Templates

The project has designed a number of templates following a particular style. This includes a Powerpoint presentation template that is to be used in all dissemination events. This will provide a uniform project image and ensure that the contribution of all partners and funding by the Commission is acknowledged.

3.10. Press Releases

Press releases (in the UK, Denmark, Italy and Germany) have already been done to coincide with the start of the project (see links below).

- http://www.ncl.ac.uk/press.office/press.release/item/pioneering-project-will-benefit-patients-with-non-alcoholic-fatty-liver-disease
- https://steno.dk/da%5Cpages%5Comsteno%5Cnyheder%5C2015%5Csteno_partner_in_epos.aspx
- http://www.cnr.it/news/index/news/id/6093
- http://www.cnr.it/news/index/news/id/6094
- http://www.almanacco.cnr.it/reader/cw_usr_view_articolo.html?id_articolo=6572&id_rub=13&giornale=6547

- www.unimedizin-mainz.de/presse/pressemitteilungen/aktuelle-mitteilungen/newsdetail/article/wie-entsteht-die-nichtalkoholische-fettlebererkrankung-von-der-diagnose-zur-therapie.html

As a result of these, considerable media interest in the EPoS consortium was generated with articles on NAFLD in the print media (UK: The Times, The Daily Telegraph, The Daily Mail, etc) and national/international news channels (UK: BBC News 24, International: BBC World).

Further press releases will be considered at appropriate stages throughout the project.

4. Networking

Use will be made of contacts through commercial partner Nordic Bioscience, and this will be linked to future exploitation activities. Commercial contacts can also be established through:

- Demonstrations, booths or specialized symposia / workshops at selected conferences, as previously mentioned
- Organizing industrial workshops about the project, inviting selected EU parties and companies (as part of exploitation efforts)
- Direct approach to experts and companies active in the field (to be based on work to be performed in the exploitation part of EPoS) such as:
    - Technology providers
    - End-users and companies in other relevant fields

Contact will also be made with other relevant EU- or national- or international-funded projects during the course of EPoS including those funded by e.g. the U.S. National Institutes of Health (NIH). Networking events organised or hosted by the European Commission, such as concertation meetings and workshops will be actively supported and exploited to make new contacts and assess opportunities for collaboration.

5. Training Strategy

To guarantee highest efficiency and best results in implementing the EPoS work-plan, researchers and industrial partners involved in the project need an in-depth knowledge of relevant technologies and capabilities of other partners. To achieve this, an internal training plan will be adopted for researchers involved in the project.

Given the diverse range of technologies and know-how that will be exploited in EPoS, training activities aimed at (a) providing new skills to researchers and (b) updating researcher skills will be organised. The structure of the EPoS project will facilitate the exchange of researchers and students, not only within their field of expertise, but also to institutes and industries outside their field of expertise. The procedures for exchange will be agreed, additional funding opportunities identified and exchange opportunities promoted internally.

6. Conclusions

This document outlines the initial dissemination plans and opportunities for EPoS. It is not intended that all details should be fixed at this early stage of the project, rather a framework has been laid and the partners will respond to dissemination opportunities which emerge. Understanding the biological and environmental factors that drive inter-patient variability within the NAFLD spectrum and the use of this information to develop robust methods for diagnosis, risk stratification and therapy is very exciting and at the forefront of current knowledge, with a lot of interest worldwide at the moment. It is clear that there will be extensive further opportunities for dissemination throughout the course of the project.