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PONTE makes research into new drugs easier and faster

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What to do when you have an idea for a new drug? Or for an existing drug to become treatment for a new disorder? How do you uncover evidence that supports your hypothesis, and how do you find the right people to test on? The researchers of the PONTE project (FP7) have created a platform that addresses those needs. You can try out the tools for free.

[1]

The PONTE platform offers vital assistance to researchers across Europe throughout each stage of the process - from the moment a researcher generates an idea for a new drug, through to the selection of suitable volunteers for a trial. As well as saving money, this will give the public quicker access to new drugs which may be able to help them.

The project involved partners from seven EU member states (Italy, Belgium, Lithuania, Greece, Germany, UK and the Netherlands) and just came to an end with good results. The EU invested about 2,5 million euros in it as part of its 7th Framework Program.

A demo of the tools is available for testing through registration at the project website: www.ponte-project.eu [2].

How it came about: Thyroid hormone

During their years of research, two experts from the field of endocrinology and cardiology – Prof Costas Pantos (National Kapodistrian University of Athens, Greece) and Dr Giorgio Iervasi (CNR Institute of Clinical Physiology, Pisa, Italy), had made the same observation: Administration of thyroid hormone in cardiac ischemia promotes cell regeneration and protects the myocardium from ischemic injury in patients with low T3.

Since the current opinion is that Thyroid hormone administration is too dangerous for patients with acute ischemia (myocardial infarction), the researchers were in the difficult situation not only to have to prove that there was a new indication for an existing drug, but also to obtain permissions to run a trial.

It was difficult to imagine how much work these two doctors had to do to uncover every little piece of evidence that would help support their hypothesis! In addition to their own research results, it would have been very helpful to have an intelligent, automatic system to do the searches through clinical and research data sources looking for evidence through clinical notes and laboratory results, animal testing reports, case reports and failed trial data, to be prompted with the possible eligibility criteria based on the profile of the investigational drug and study disorder, to be assisted through a flow of study parameters directly linked with literature, etc.

Even though the pharmaceutical industry has invested in the development of IT systems that can search and match data, there was little commercial interest to pursue this specific idea and facilitate a trial for an existing and inexpensive off-patent drug for an indication that was considered risky.

From a medical perspective however, research into this observation had the potential to revolutionize treatment and improve outcomes of the subset of patients with low T3 and myocardial ischemia.

Not easy to set up a study

Even in the presence of a sponsor it would not have been easy to set up a study because it was important to assess the potential recruitable number of patients for this specific study. In addition to having an acute myocardial infarction the potential trial subjects had to have a reduction in active T3 as well. This meant that the medical records of patients would have to be searched for the simultaneous presence of several abnormal findings to identify suitable patients.

This is a very common need in trials which is not addressed well at present. Current clinical data bases do not routinely feature this functionality and by no means are there systems allowing for the translation of study eligibility criteria into a series of parameters recorded in healthcare. The facilitation of such clinical record search would help estimate the viability of a trial, automatically identify suitable patients and avoid delays.

This is what led to the concept for the creation of the PONTE platform: To design an integrated system which could help researchers generate and test a hypothesis via an intelligent search engine which links data from various sources and a series of mechanisms which extract all the available evidence, support the researcher in the preparation of the clinical trial protocol and facilitate the assessment of the available sample size on the trial sites and the identification of suitable trial subjects.

Search, query and decision support tool

The PONTE platform is designed to act as a one-stop search, query and decision support tool. By linking to existing medical knowledge databases, it gives near-instant access to information about any disease, drug or target properties. This will aid researchers as they develop their hypotheses for new applications of existing medicines. If, for example, there is the possibility that a particular drug used for one disease may be useful in treating another disease, PONTE will help to uncover it.

The platform enables interrogation of data stored by individual hospitals to establish whether sufficient patients meet the criteria for a trial to be able to proceed. PONTE can select pre-consenting volunteers immediately – ensuring the right people for the right trial at the right time. To complete the jigsaw, the system also provides a step-by-step guide for setting up a clinical protocol, in turn ensuring all aspects have been completed well in advance of the start of the trial.

The PONTE platform comprises an integrated product combining several components, which can be exploited each on their own merit.

The Intelligent Data Search Tool: GoPONTE

The GoPONTE engine was developed by TUD, in collaboration with ICCS/NTUA and CETIC, in the framework of the PONTE EU project. It is an Ontology Based Search Engine (OBSE) with a Linked Data Application for searching efficiently not only at targeted sources of biomedical literature and clinical findings but also across the Web.

GoPONTE supports the researchers during their search with a mechanism to extract the most relevant concepts and bookmark the results. This is useful both for the hypothesis creation as well as in the process of the clinical trial protocol writing.

GoPONTE has been found to perform favourably against other state of the art engines, such as PubMed and Google Scholar during the evaluation. The search engine can be placed in any academic and commercial environment, can be linked to their preferred data bases and extract results.
The framework of the tool is currently used in two recently started EU projects -OpenScienceLink and BioAsq for the development of further search functionalities.

The Clinical Trial Protocol Authoring Tool

The Clinical Trial Protocol Authoring Tool features a standard protocol template with advanced decision support and through GoPONTE it allows the bookmarking of the relevant results per protocol section by the users of the PONTE platform, so that they can work independently and at different time spans on the design of a study protocol.

Its unique features are that it is flexible, allows multiple authors and good tracking of versions and that it keeps records of the results of all data searches and allows to trace back reasons for specific decisions during protocol writing. The decision support mechanisms covering automatic questions generation for literature searches and eligibility criteria suggestions.

The tool can be placed in any academic and commercial environment and the template can be enriched with specific requirements of the user.

The Healthcare Patient Data Query Tool

This tool encapsulates a series of novel mechanisms and models for translating eligibility criteria of clinical trials into patient data parameters which can be found in healthcare databases and is complemented by mechanisms for data protection. The tool has a threefold application in the trial design and recruitment process:

- for the sample estimates as well as for evaluating study site recruitment potential – through the estimation of number of eligible patients per center;
- for the actual selection of eligible patients for recruitment and;
- for an automatic, intelligent pre-screening of the selected eligible patients –based on the available data- on the basis of patient safety and study efficacy.

Hence, this tool facilitates automated search in databases with patient data: hospital database, cancer registries (both to comply with data protection regulations), volunteer registries etc. Search in databases for recruitment purposes should only be done if the patients have consented to data search of their medical files for research purposes.
The tool can be used for any clinical data base interrogation needs, not only for the purposes of

recruitment but also for any epidemiological and statistical enquiries.

THIRST – the pilot study

This study has the potential to bring groundbreaking evidence for novel treatment of heart failure and to open the doors for further research on the effects of thyroid hormone in a wide range of clinical scenarios
The preliminary results are:

- Treatment with synthetic thyroid hormone replacement therapy with a triiodothyronine analogue (liothyronine, Liotir, IBSA) is safe and feasible in patients with STEMI both in the acute (in hospital period) and chronic phase (till 6 month after hospital discharge);
- Thyroid hormone therapy appears to reduce infarct size, regional wall motion abnormalities, systolic and diastolic myocardial dysfunction; also neuroendocrine imbalance (in particular nor adrenaline pathway)is improved as well as quality of life, cognitive and behavioural status.

These preliminary, but promising results suggest that studies on the role of thyroid hormone treatment in preventing progression of cardiac dysfunction after an acute ischemic cardiac event should be expanded. This would have significant implications for the health care industry and society.

The PONTE consortium (based in Italy, Belgium, Lithuania, Greece, Germany, UK and Netherlands) is committed to support any interested users of the platform and its components. For further information please contact the coordinator Philippe Massonet at philippe.massonet@cetic.be [3]

www.ponte-project.eu [2]

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