Ponte

Efficient Patient Recruitment for Innovative Clinical Trials of Existing Drugs to other Indications

www.ponte-project.eu

Ponte Project Partners

Cambridge University Hospitals NHS Foundation Trust

Ocetic Your Connection to ICT Research

biotec

ΕΠΙΣΕΥ ICCS

IFC CNR

SSM Strategic Medicine

National and Kapodistrian University of Athens

Leibniz Universität Hannover

Grant Agreement No. FP7-247945

Project Summary

*Clinical trials are considered not only a means for evaluating the effectiveness of new medicine and pharmaceutical formulas but also for experimenting on existing drugs and their appliance to new diseases and disorders (**drug repositioning**). However, translation into clinical therapy has to overcome substantial barriers at the preclinical and clinical levels. Indeed, currently clinical research findings quite often substantially deviate from the outcome of the treatments' application to healthcare, whereas efficacy of treatments under investigation may be lost in translation. Data collection poses a significant challenge for clinical investigators; a great amount of medical information crucial to the success of a clinical trial remains hidden inside a variety of information systems and data sources that do not share the same semantics nor adhere to widely deployed clinical data standards.*

Within this framework, PONTE aims at providing a platform following a Service Oriented Architecture (SOA) that will offer efficient study design and intelligent selection of patients eligible to participate within drug repositioning trials with specific focus on mitigating patient safety risks, reducing clinical trial costs and improving study efficacy. Work towards this direction involves the development of advanced decision support mechanisms which will be fed with information intelligently retrieved from an innovative semantic search engine operating on top of a novel data representation with excessive descriptive power linking data within drug and disease knowledge databases, clinical care and clinical research information systems by following and extending existing standards.

PONTE Project Objectives

PONTE aims at developing a set of intelligent mechanisms fed by highly descriptive semantic representations of the data involved in the clinical trial lifecycle in order to:

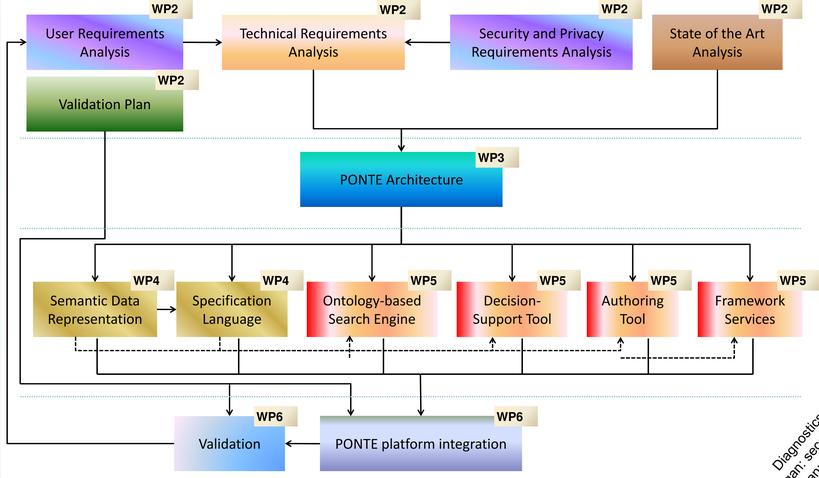
- Enable the development of a research question into a clinical trial through test of hypothesis validation
- Efficiently guide clinical researchers through clinical trial protocol preparation through advanced decision support at multiple steps, intelligent queries to distributed heterogeneous data sources and advanced navigation - beyond a simple view - through the clinical trial protocol
- Offer effective automatic selection of individuals eligible with a clear focus on patient safety, clinical trial efficacy and cost
- Allow for adaptive clinical trial design.

✓ **Improvement of study efficacy**

✓ **Mitigation of patient safety risks**

✓ **Reduction of study costs**

PONTE Project Work Plan



PONTE Pilot: the THIRST Study

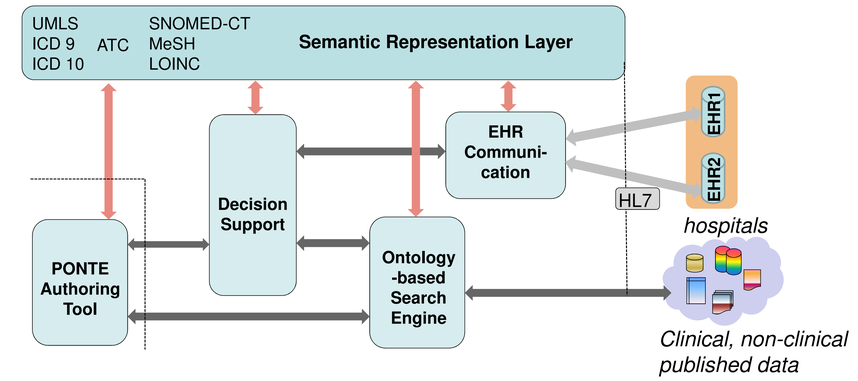
Thyroid hormone, given its pleiotropic actions, may be the basis of new treatments in heart failure aiming rather to promote physiological hypertrophy than the current treatments focusing on inhibiting pathological hypertrophic pathways. The PONTE pilot is a Phase IIB study for investigating safety and feasibility of thyroid hormone (TH) replacement therapy with synthetic triiodothyronine in patients with ST-Elevation Myocardial Infarction (STEMI).

The Clinical Research Landscape

Average Drug Development cost € 500-700 million per drug candidate - timeline >10 years

- Tremendous reduction in new active ingredients reaching the market yearly
- Clinical trials account for ~ 1/3 of the costs of drug
- Low recruitment rates – Long recruitment periods
- Subjects recruited represent only partially the target patient population
- Mortality rates in clinical study findings vs real life
- 1 out of 5000 new drug candidates reach the market

PONTE Overall Architecture



PONTE Expected Outcomes

✓Highly descriptive, consistent models leading to a rich PONTE Ontology capturing a wide variety of important concepts and various steps in clinical trial design, including test of hypothesis validation, protocol design and patient selection;

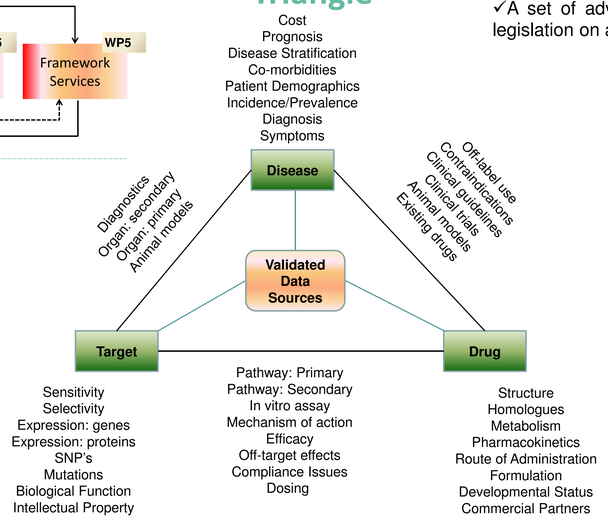
✓A set of novel mechanisms and tools for enabling semantic interoperability between the clinical research and the healthcare domains based on the PONTE Ontology and a wide set of available codings, terminologies, vocabularies on drugs, diseases and lab tests including SNOMED-CT, UMLS, ATC, ICD10, LOINC among others as well as health messaging standards such as HL7

✓An innovative Ontology-Based Search Engine able to mine information based on the PONTE ontology which will incorporate the Linked Data approach and allow the querying of and navigation through a great variety of heterogeneous (in terms of syntax, structure, type, content, semantics, interfaces) data sources including EHRs, drug and disease information sources and clinical research findings;

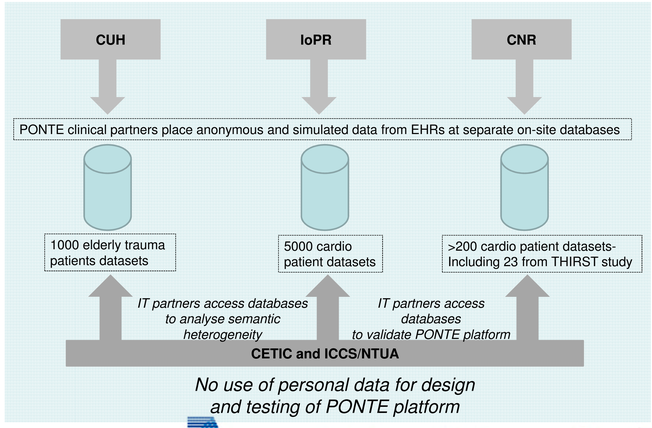
✓A set of intelligent decision-support services covering the clinical trial protocol design and the patient selection phases with a clear focus on increasing clinical trial efficacy, strengthening patient safety and reducing trial costs;

✓A set of advanced authentication and data confidentiality mechanisms aligned with current legislation on access to and use of patient health data for the purposes of PONTE.

PONTE Knowledge Triangle



PONTE Validation Phase: Project Lifetime



This project is partially funded by the European Commission under the 7th Framework Programme

SEVENTH FRAMEWORK PROGRAMME

eHealth

European Commission Information Society and Media