PONTE

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

PONTE will develop and validate a universal platform which will support clinical researchers in the generation and testing of hypotheses for drug repositioning trials, evaluation of their commercial viability, guidance and decision support in the creation of the Clinical Trial Protocol.

Objectives of the project

New drug development is costly, slow and is hampered by safety issues. Researching the use of known drugs for new indications has become a timely strategy for the pharmaceutical industry and has been found to offer faster, cheaper and safer solutions.

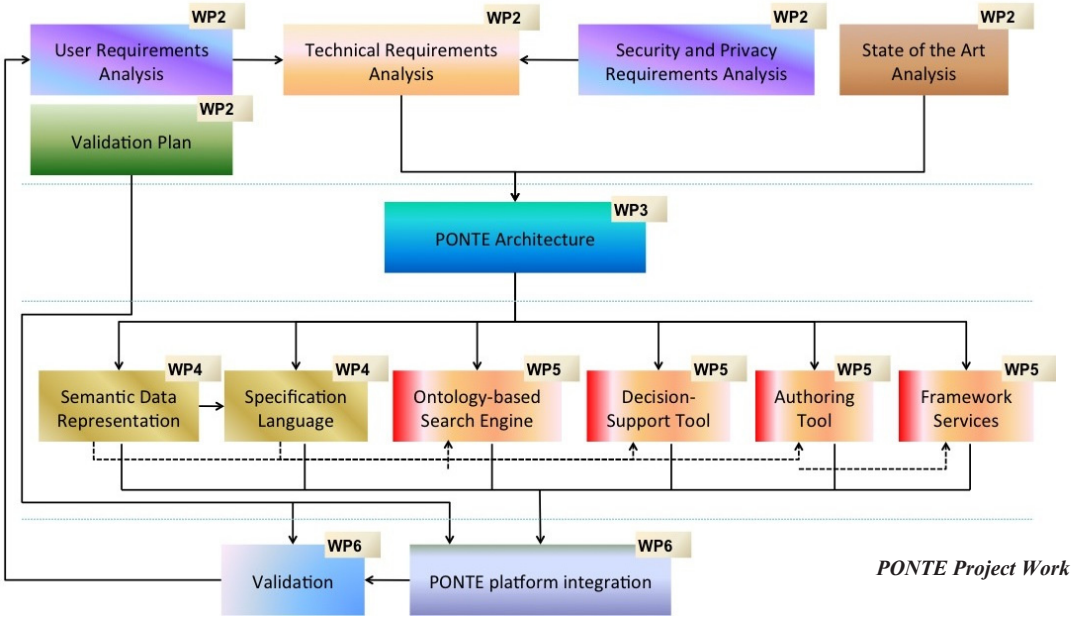
In line with the current commercial and societal needs and the ICT research objectives, PONTE's goal is to aid drug repositioning research by developing technology to securely and consistently link clinical care information systems with clinical trial systems, improve their semantic interoperability, define and validate the required core data sets and create mechanisms for adequate data protection.

More specifically PONTE aims at developing a set of intelligent procedures linking descriptive semantic representations of data involved in the clinical trial lifecycle to:

- Enable the development of a research question into a clinical trial through the comprehensive testing of the hypothesis across the clinical, molecular and commercial domains.
- 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 through the clinical trial protocol.
- Enable effective automatic identification of eligible individuals while focusing on patient safety, clinical trial efficacy and cost
- Support adaptive clinical trials.

Project Description

The PONTE architecture links heterogeneous data sources, such as clinical data (Electronic Health Records), clinical trial data, drug and disease knowledge data bases with an innovative ontology based search engine.



PONTE Project Work Plan

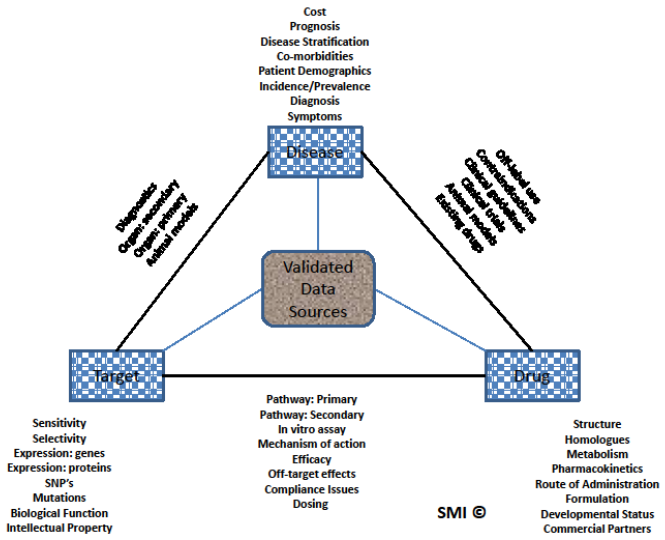
PONTE develops advanced tools for semantic interoperability between these data, which take into consideration all widely used standards, such as coding systems, terminologies, vocabularies on drugs, diseases and lab tests including SNOMED-CT, UMLS, ATC, ICD10, LOINC among others as well as health messaging standards such as HL7.

At the user interface the researcher is able to interact with the platform and directly submit queries required for the research hypothesis generation and validation.
Behind the user interface the queries are directed to the relevant concepts related to drug research which are linked to the PONTE ontology and the data sources.

CASE STUDY

THIRST is based on an existing, multi-center clinical trial examining the effect of thyroid hormone in patients with acute myocardial infarction. Based on previous research evidence, this drug repositioning study aims to take treatment of acute myocardial infarction into a new paradigm. The scenarios provide vital insight into the components of a clinical trial setup. During the validation phase PONTE re-evaluates the conversion of the original hypothesis into the clinical trial protocol. By "reverse engineering" both the PONTE functionalities, as well as the completeness of the THIRST clinical trial design are tested and critically evaluated.

Ontology concepts of drugs repositioning



A set of tools for intelligent queries links PONTE with clinical data sources to assess the potential sample size and eligible patients for recruitment.
For the purposes of use of patient data during the development and exploitation phases of PONTE, advanced authentication and data confidentiality mechanisms are developed, to ensure that all data handling is in line with current international and national legislations.
PONTE guides the researcher effectively through every step of the creation of a clinical trial protocol through an authoring tool and mechanisms for advanced decision-support.

The user scenarios of the pilot study THiRST, as well as anonymised clinical data bases provided by all clinical partners, serve as a foundation for the creation of the PONTE tools and for their initial validation. The PONTE partners collaborate from early stages of the project with pharmaceutical and clinical research partners to re-examine concepts and clinical trial protocols of attempted drug repositioning trials with the help of the platform, thus aiding to its further development and validation.

Expected Results & Impacts & Preliminary results

PONTE will provide clinicians with new methods for accessing information to prepare, design and select patients eligible for recruitment for drug repositioning trials.

Pharmaceutical companies will benefit from earlier and more reliable go/no-go decisions and earlier identification of risk of failure. Designing drug repositioning trials through the PONTE platform will help increase the clinical trial efficacy, mitigate patient safety risks and reduce trial costs.

PONTE will further stimulate drug repositioning research and will help recover commercial value from previous expensive research investment.

At the research institutions PONTE will facilitate faster and safer design of drug repositioning trials, allowing for early and more precise estimates of the likely cohort size of eligible patients.

Patients will benefit from the results of drug repositioning research faster. At the same time repositioned drugs are likely to be safer for the patients than newly developed compounds.

Stakeholders from the pharmaceutical industry and international data providers who would interface and integrate their data with the PONTE platform for commercial exploitation will gain a competitive edge.
Initial results and a mock-up are available on PONTE website.

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