Ponte

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

www.ponte-project.eu

http://cordis.europa.eu/fp7/ict/
http://ec.europa.eu/information_society

eHealth

Cambridge University Hospitals NHS

An Innovative European Funded Project for Drug Repositioning Research

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Director, EU Funded Projects

European Commission Information Society and Media

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

Why PONTE

- Global crisis → ↓↓↓ funding for research
- New drug development is hampered by:

❑ ↑↑↑ Costs = 2 x in 10 years

❑ ↓↓↓ Return Of Investment by 50% in10 years

❑ Long duration of development >10 years

❑ Risk of post marketing drug failure

❑ Risk of failure of clinical applicability

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Drug Repositioning

Is a timely strategy

Offers faster, cheaper and safer solutions.

PONTE

Aims to optimise drug repositioning

Has a strategic place in the current pharmaceutical market environment

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PONTE platform objectives

- 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

Expected Impact

- Mitigation of patient safety risks
- Improvement of study efficacy
- Reduction of study costs

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Stakeholders

- Pharmaceutical companies
- Research Institutions
- Clinicians
- Patients
- Society

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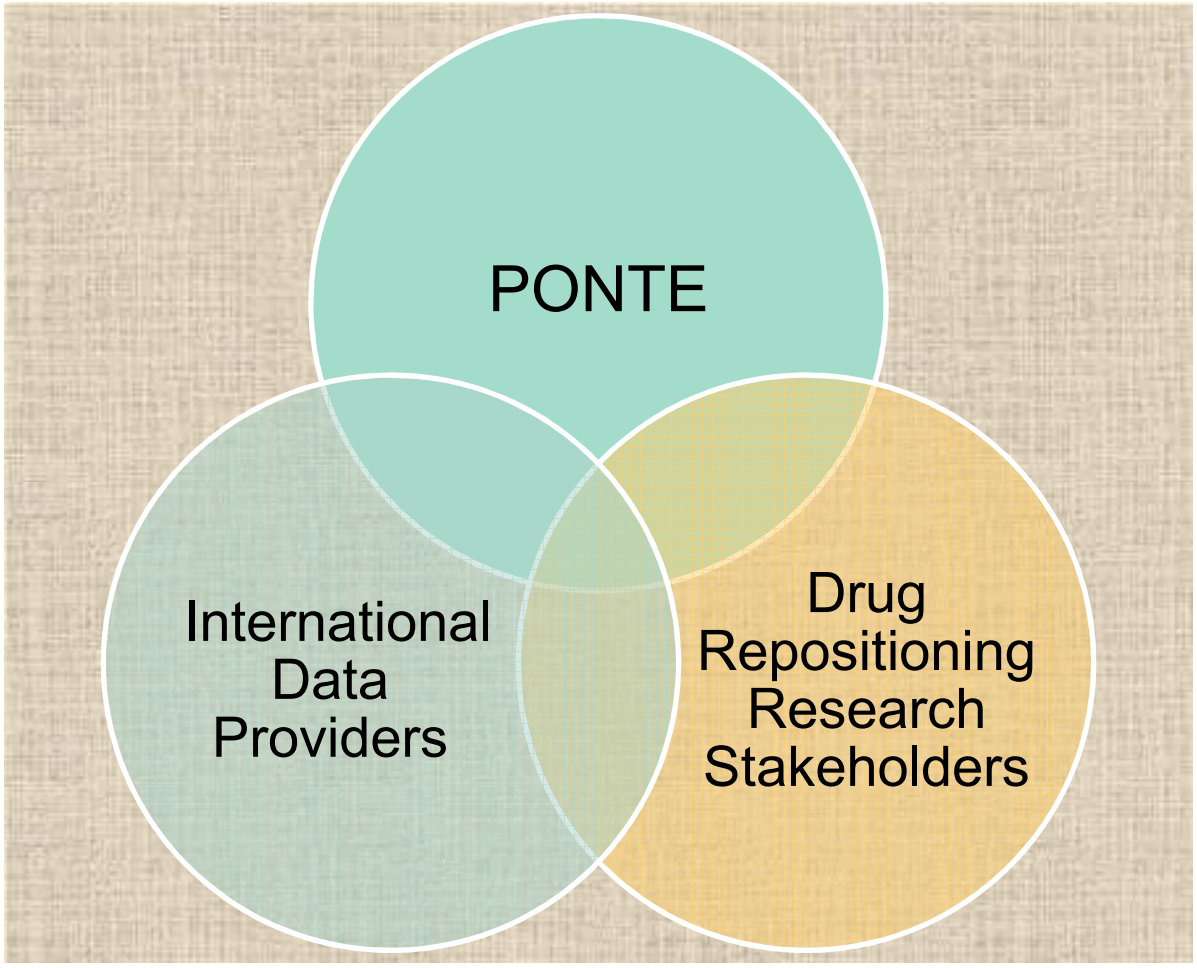
Exploitation

Ponte's Service Oriented Architecture will be designed to be attractive for collaboration with major international data providers for strategic interfacing and integration of their data with its platform in order to ensure commercial success



Commercial Users
Academic Users

Stakeholder Analysis

Stakeholder	Interest / stake in PONTE platform	Importance for PONTE platform dissemination	Interest/ stake in thyroid trial	Importance for T4 dissemination
Pharmaceutical Companies	Hypothesis testing to generate new ideas Faster and cheaper drug trials	high	Potential for thyroid hormone to become a competitor in treatment of myocardial ischemia	moderate
Data source companies	Partnership with PONTE for access to content of knowledge data bases	high	Enrichment of own data from the results of the pilot study	low
Clinical Trial Units	Support for • Hypothesis generation • Clinical trial protocol design • Selection of eligible patients • Faster and cheaper trials, efficient effort	high	Variable From opposing to supporting for the innovative treatment concept	moderate
Other researchers	Use of platform for hypothesis generation and creation of clinical trial protocols	moderate	Variable From opposing to supporting for the innovative treatment concept	high
Clinical staff	Use of platform for hypothesis generation and creation of clinical trial protocols	moderate	Variable From opposing to supporting for the innovative treatment concept	moderate
Academic teaching staff	Use of platform for hypothesis generation and creation of clinical trial protocol	moderate	Variable From opposing to supporting for the innovative treatment concept	high
Software developers or vendors	IT for clinical databases	high	N/A	N/A
Management and Administrators	Efficient use of clinical data for attracting research funds Innovative Tool for extracting statistical data	moderate high	Potential for more cost effective treatment and better health outcomes	low
Other project consortia in the field	Collaboration between projects	moderate	Extension of the trial concept	low
Funding authorities	Potential for hospitals to attract more research	moderate	Potential for more cost-effective treatment of patients with myocardial ischemia	low
Publishers	Innovation attracting high interest	high	Innovative potential treatment	moderate
Patient organisations	Innovative approach to speed up research	moderate	Potential for new treatment	moderate
Wider public	Innovative approach to speed up research	low "word of mouth effect"	Potential for new treatment	low

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- 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

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Benefits

- PONTE after completion allows for
  - Full search for hypotheses for repositioning of drugs
  - Fast check for feasibility of setting up a trial
  - Decision support for clinical trial protocol
  - Support with selection of eligible patients

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Collaboration during PONTE development

- Clinical trial units can test PONTE platform
  - Check own drug repositioning trials if methodology correct
  - Check unsuccessful drug repositioning trials if can be redesigned correctly and revived
- Clinical trial units are invited to validate the platform by test using it

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Special Interest Groups

- Provide **guidance** towards the development and relevance of the PONTE project for successful commercial exploitation.
- Enable real **customer needs to be analyzed** in light of PONTE's technical strengths as well as prioritize novel technological opportunities with respect to potential customer acceptance.
- The expected **result is to align PONTE's concept to the real market need**, thus - when completed, to become a competitive product which will bring real value to drug repositioning research and clinical trial design, overall.

SIG MEMBERS PONTE

- Dr. **Sandor Szalma**, Senior Research Fellow and Head of External Innovation, R&D IT in Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
- **Clarke Golestani**, CIO, Merck Pharmaceuticals
- Dr. **Rene Schaik**, Head, Informatics, Organon/S-P/Merck
- Dr. **David Searles**, former Sr. VP, GSK Pharmaceuticals, SAB EU IMI OpenPhacts
- Dr. **Franklyn Prendergast**, MD, PhD, Head of Inst for Personalized Medicine, member Board of Governors, Mayo Clinic, Rochester, Minnesota , (also on Board of Dir of Eli Lilly, Pharmaceuticals)
- **Michael Briggs**, PhD, Senior Director, Head of China Development, Vertex Pharmaceuticals, Boston, MA
- Dr. **Tomas Votruba**, PhD., MBA, Gen. Manager, Roche Pharma. (Czech Rep)
- Dr. **Andreas Materan**, VP, Technical Sales Healthcare and Science, Thomson Reuters Life Sciences
- **Philippa Smit-Marshall**, MBChB, BSc, FFPM, FICR, Vice President and General Manager Paediatrics and Medical Sciences,PharmaNet

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Special Interest Groups activities

- Initial and ongoing **review** of PONTE development plans and goals
- **Evaluation** of current state of the art
- **Input** into functional requirements for PONTE platform based on user needs
- Review of PONTE manuscript(s) on scenario-based hypothesis development and refinement; platform development; technological advances
- Participate in **virtual meeting(s)**
- Participate in **face-to-face meeting(s)** during year 2 of PONTE

Letter from Potential Client

From: Szalma, Sandor [ORDUS] [mailto:sszalma@its.jnj.com]
Sent: Friday, May 13, 2011 5:01 PM
To: Michael Liebman
Cc: Venkatachalam, Sai [PFSUS]
Subject: protocol reverse engineering

Dear Michael,

We are very much interested in an introductory discussion about your experience in PONTE and how it can translate to improved protocol writing. Can we set up a virtual meeting over the next couple of weeks to discuss this topic?

Best regards,

Sándor

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eHealth

SEVENTH FRAMEWORK PROGRAMME

Cambridge University Hospitals NHS
NHS Foundation Trust

Thank you for your Attention

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