p-medicine – From data sharing and integration via VPH tools to personalized medicine

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Introduction

Medicine is undergoing a revolution that is transforming the nature of healthcare from reactive to preventive. The changes are catalyzed by a new systems approach to disease, which focuses on integrated diagnosis, treatment and prevention of disease in individuals. This will replace our current mode of medicine over the coming years with a personalized predictive treatment [1]. While the goal is clear, the path is fraught with challenges. The emphasis of *p-medicine*, a large integrated project, funded by the European Commission under the 7th Framework Programme, is to pave the way to personalized medicine by building an infrastructure that can be exploited in daily clinical care.

Rationale for p-medicine

Multi-level data collection within clinico-genomic trials and interdisciplinary analysis by clinicians, molecular biologists and others involved in life science is mandatory to further improve the outcome of cancer patients. The problem of sharing clinical data presents a major hurdle for the facilitation of research using such data.

Clinical trials are essential to achieve better treatments for patients. The recruitment rate of patients into clinical trials is currently low despite recognized better outcomes. The enrolment process is slow and inefficient, involving redundant data entry, inconsistencies and several manual verification steps. As a result of the Clinical Trials Directive 2001/20/EC the conduct of clinical trials throughout Europe has recently changed [2, 3, 4]. The directive, aimed largely at holding pharmaceutical companies to higher standards, has tied up academic clinical research, particularly for large trials, with redundant and highly time consuming paperwork, liability tangles and unending bureaucracy [4].

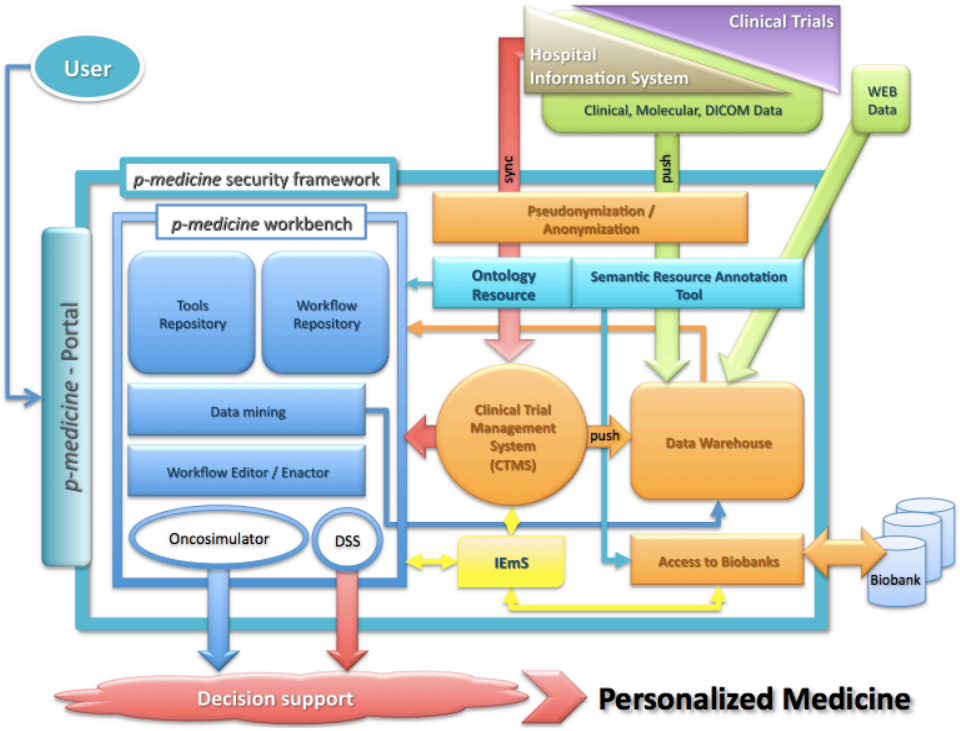
In Silico Oncology

Research in VPH has not reached an acceptable level of maturity to be used in clinical routine. Especially in cancer this is a highly demanding endeavour. Following clinical adaptation and validation within the framework of clinico-genomic trials, models are expected to enhance individualized treatment optimization. Treatment optimization is to be achieved through experimentation *in silico* i.e. on the computer.

Objectives and expected results of p-medicine

Scenarios and structures that help to run more clinical trials and to bridge the gap between treatment given to patients today and research to find better treatment for patients is of utmost importance. **In consequence, the *p-medicine* project proposes to create a clinically driven infrastructure that will support the advance from the current medical practice to personalized medicine.**

Fig. 1.: Clinical perspective of the p-medicine architecture



In *p-medicine* three categories of scenarios under which data need to be accessed and shared will be addressed:

1. the composition of large, pseudonymized/anonymized datasets from multiple sources including clinical trials, used to perform inductive reasoning for example,
2. the collaborative development and validation of new VPH models and simulators, and
3. the use of data obtained from a single patient to run a simulation workflow in support of a clinical decision making process.

To succeed in achieving the goal of personalized medicine *p-medicine* has the following **objectives**:

1. To create a collaborative environment facilitating clinically driven multiscale VPH modelling leading to personalized medicine
2. To foster the development, sharing and running of VPH simulations for clinical decision support by
   a) Building a data warehouse for the secure storage and sharing of heterogeneous data to be used by the scientific community
   b) Building a *p-medicine* workbench as a central access point for tools, models, services workflows and to data resources
3. To exploit the potential of high performance computing and cloud storage for the use of VPH models and data services
4. Improve the semantic interoperability and data integration
5. Deploying clinical trials for VPH adaptation and validation purposes
6. Increase the quality of data mining in biomedical research
7. Establish a service framework for access to biomaterial resources
8. Empower patients through respective tools, which involve them more actively in the health care decision process and in clinical research

9. Link the *p-medicine* environment with important European Research infrastructure initiatives
10. Develop training and educational eLearning tools for end-users to foster VPH models for decision support
11. Develop a business plan to maintain and further develop *p-medicine* into a self-sustaining entity

Conclusion

The approach presented in this paper will develop an infrastructure that allows the seamless joining and sharing of vast amounts of heterogeneous data within a legal and ethical framework. Tools, models and services will be provided that helps clinicians in decision support to pave the way to personalized medicine. The project is clinically driven. Maintenance beyond the funding period of the project is a realistic goal, since tangible results for clinicians are awaited.

Acknowledgement

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