Project Context

TRANSFoRm aims to develop the technology that facilitates a learning healthcare system. Three carefully chosen clinical use cases will drive, evaluate and validate the approach to the ICT challenges of embedding diagnostic decision support and clinical trial workflow into the EHR and providing a secure infrastructure for large scale genotype-phenotype studies using primary care data. The project builds on existing work at international level in clinical trial information models (BRIDG and PCROM), service-based approaches to semantic interoperability and data standards (ISO11179 and controlled vocabulary), data discovery and machine learning. The approach to system design is modular and standards-based, providing services via a distributed architecture. This five year project will have four years of development and testing and will end with a fifth year dedicated to summative validation of the project deliverables in the Primary Care setting.

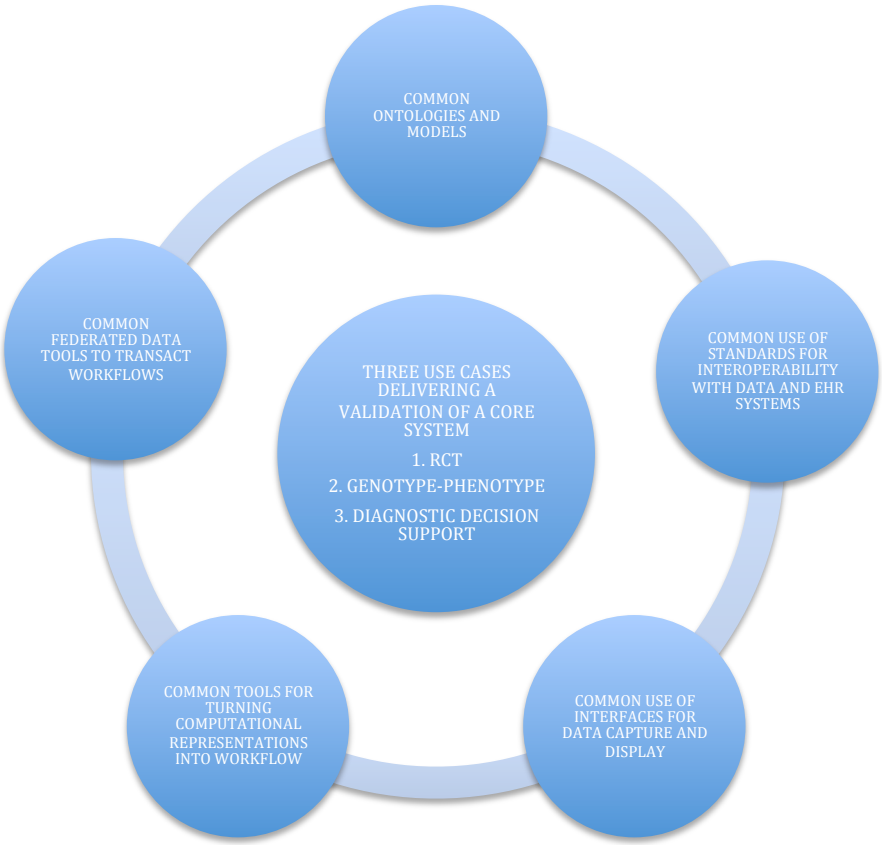

Figure 1 - Concept of TRANSFoRm

Principal project outputs

The TRANSFoRm project is based around the achievement of 12 core outputs that are essential to project impact. Progress towards these outputs is linked to deliverables over the 5 years of the project, some relating to individual work tasks, others to the result of a series of work tasks.

1. **SEMANTIC MEDIATOR** A web-service for terminology mapping available for this and similar projects (WT 7.2). This is an essential component of the system for semantic mediation of data at the point of care. TRANSFoRm will NOT be aiming to create and manage a mapping of minimum datasets for interoperability but will be working with the extension of already maintained reference terminology (via UMLS), presented as a service throughout the project infrastructure.

2. PRIVACY MODEL A generalizable model for privacy based on EU data protection laws (WT 3.1, 3.2). This model will underpin the operation of the security framework and implementation as well as the flow of data and authorization of access to data in the system.

3. PROVENANCE A service for managing provenance of EHR data obtained for research purposes (WT 5.4) is essential for validating data quality and auditing compliance with the privacy framework.

4. DATA QUALITY A model for assessing data quality in EHR systems and repositories with a tool for applying it (WT 5.1) is an essential part of validating the re-use of clinical data for research purposes.

5. SQA AND INTEGRATION Satisfactory Quality Assurance and software integration and testing procedures to enable use in research settings (WT3.5).
6. EXPLOITATION A technical exploitation and business model for the further development of the DSS proof-of-concept and research systems into use within European EHR systems (WT 9.1)

7. CLINICAL PREDICTION RULE WEB SERVICE A web service for clinical prediction rules (CPR), based on an ontological representation of clinical cues and differential diagnoses arising from a presenting clinical problem (WT 4.4).

8. RESEARCH DATA INFORMATION MODEL A standard for a computable representation of the operational elements of a clinical study protocol (WT 6.5, 6.6). This enables an xml document to be authored using a semantic research workbench that binds selected terms provided by the terminology service to a data model. The document will contain all the elements necessary to transact a study (eligibility criteria, data elements, timelines and interventions).

9. ELECTRONIC CASE REPORT FORM (eCRF) An interface for integrating clinical prediction rule data capture and research data element capture (via a functional eCRF) into the EHR. This is a common process and consists of both a functional prototype and a set of specifications for implementing in an existing EHR framework (WT 5.2, 5.3, 7.4).

10. DATA FEDERATION Middleware for transacting research workflow in distributed heterogeneous EHR systems and data repositories (WT 7.2).

11. RESEARCH EVALUATIONS Research papers in major journals describing well-designed and adequately powered evaluations of the use of the software tools (WT 1.4,1.5).

12. DECISION SUPPORT PROTOTYPE Research papers describing well-designed experiments to design and evaluate a pilot decision support service for diagnosis that integrates with clinical cognitive workflow (WT 2.2, 2.3, 2.5).

Expected final results and their potential impact and use

The aim of TRANSFoRm is to develop a 'rapid learning healthcare system' driven by advanced computational infrastructure that can improve both patient safety and the conduct and volume of clinical research in Europe. The EU policy framework for information society and media, i2010, identifies eHealth as one of the principal areas where advances in ICT can create better quality of life for Europe's citizens. ICT has important roles in communication, decision-making, monitoring and learning in the healthcare setting. Providing interoperability between different clinical systems, across national boundaries, and integration of clinical systems and research systems lies at the heart of the eHealth Action Plan, 2004. This is however, a two-way street, just as clinical data are needed for research (for participant identification and evaluation of outcomes), research data is needed to support clinical care. Furthermore, advances in the understanding of clinical judgment and decision making, and the possible ways of supporting them via ICT can inform the design of more 'intelligent' electronic health record systems. The TRANSFoRm project will achieve its impact via exploitation of the principal study outputs listed above. Work Package 9: Dissemination and Exploitation will lead the engagement of exploitation partners throughout the project and be responsible for the creation and maintenance of an exploitation strategy, which is delivered in the 2nd year.