PROJECT PERIODIC REPORT

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Project acronym: TRANSFoRm

Project title: TRANSLATIONAL RESEARCH AND PATIENT SAFETY IN EUROPE

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Periodic report: **1st ☑ 2nd □ 3rd □ 4th □**

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1 Publishable summary

Objectives

TRANSFoRm aims to develop the technology that facilitates a learning healthcare system (see Figure 1). Three carefully chosen clinical 'use cases' will drive, evaluate and validate the approach to the ICT challenges. The project will build 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, machine learning and electronic health records based on open standards (openEHR). We will extend this work to interact with individual eHR systems as well as operate within the consultation itself providing both diagnostic support and support for the identification and follow up of subjects for research. The approach to system design will be modular and standards-based, providing services via a distributed architecture, and will be tightly linked with the user community. Four years of development and testing will end with a fifth year that will be dedicated to summative validation of the project deliverables in the Primary Care setting.

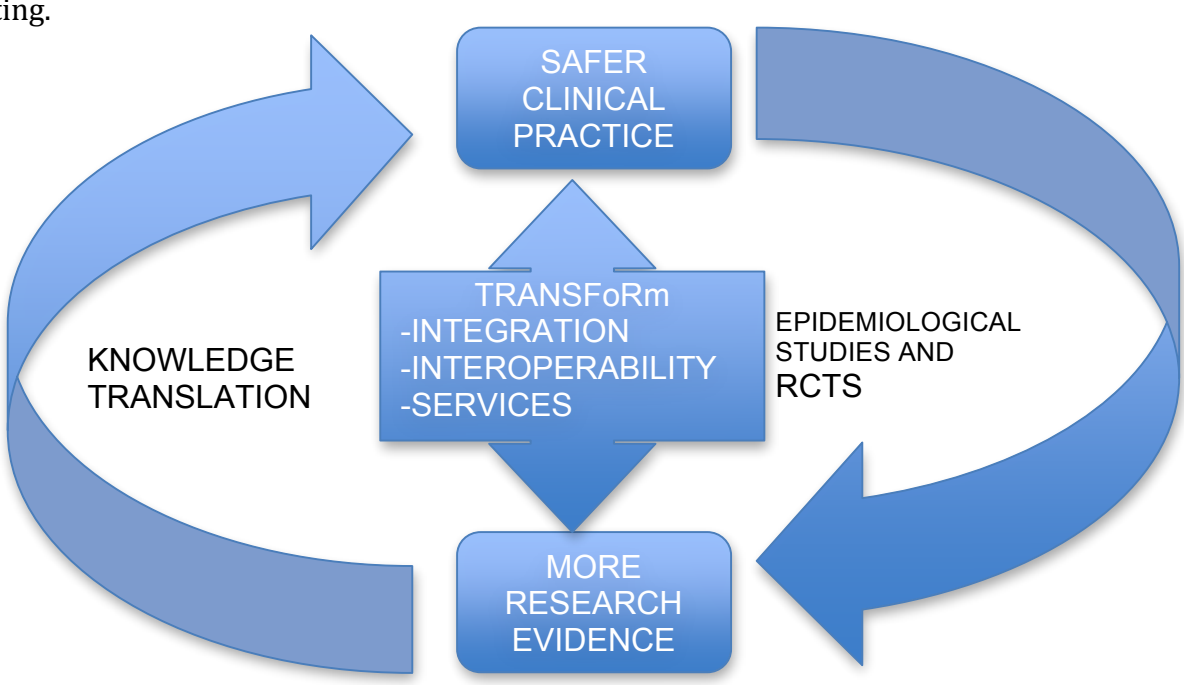

Figure 1: *Concept of TRANSFoRm*

Summary of project objectives

1 Validation in well-defined research use cases: To develop and validate the software and services in the context of two representative research use cases (a genomic-phenotype study and an RCT).
2 Validation in a Patient Safety use case: To provide a detailed use case for the development of a decision support system for diagnosis in Primary Care (SO4) will require the development of more detailed user requirements based on an investigation of potential types of support and their timing during the consultation.

3 Data protection: To ensure that systems to integrate clinical and research data are built in full compliance with all legal and ethical requirements at European level, a systems user-centred security policy is required.
4 Supporting learning and decision-making: To support the development of an active learning healthcare system knowledge will require structuring according to both clinical domain ontology and a specific ontology relating to the combination of data for clinical diagnosis.
5 Support semantically rich data capture in both research and clinical practice: For clinical care it means developing a dynamic interface, driven by the ontology of SO4 that increases the detail of capture and semantic richness of coding to support diagnostic decision support and reuse of the data in research. For research, it means developing dynamic interfaces to support, with ease, the vocabulary tools for data integration and the specification of metadata for common data elements.
6 Communication between research and clinical systems: Syntactic (model-based) and semantic interoperability based around the definition and validation of a core data set by means of the US National Cancer Institute's Enterprise Vocabulary Service, with core concepts expressed via the Unified Medical Language System (UMLS), and mappings created to a variety of clinical nomenclatures, including SNOMED-CT and ICD10.
7 Development of a modular set of tools and services: A service and agent based distributed middleware will be developed to manage secure connectivity to clinical databases and electronic health record systems, and to manage distributed searches and data mining across the system.
8 Demonstration: To engage target users beyond the project consortium in planning for, testing and evaluating the systems for their user group.
9 Dissemination and exploitation: To develop and implement a strategy for the sustainability of the systems and tools.

Work performed since the beginning of the project

The TRANSFoRm project has just completed its first year and has made substantial progress towards study objectives 1,2,3, and 6. The initial Work Packages have started work and regular project meetings have been held as progress has been made towards the first year deliverables and milestones. WP1 has conducted a survey of research capacity in European Primary Care, including the availability of data repositories using data from Primary Care electronic health records, genetic databases and cancer registries that could be linked. Two detailed use cases have been developed (D1.1):

1 A genotype-phenotype study in Type 2 diabetes using routine data and SNPs to investigate a) the risk of complications of Type 2 DM b) response to oral sulfonyl urea.
2 Gastro oesophageal reflux disease (GERD), and PPI use. a) A case control study of the effect of PPI usage on the development of oesophageal cancer, b) an RCT of on-demand v continuous PPI in GERD with consultation-driven patient related outcomes (symptoms and quality of life).

WP3 has worked with D1.1 and an investigation of regulatory requirements, confidentiality and data privacy issues to derive a 'zone model' for managing data privacy (D3.2). In addition, simultaneous analysis of the developing privacy model and D1.1 has led to the development of a provenance model (D3.1) and a security policy (D3.3). A draft software quality assurance framework has been agreed (Milestone 4).

WP6 has contacted a variety of eHR vendors, data repositories, cancer registries and genotype repositories, to obtain further information as to the readiness of these data holders to meet the requirements of the use cases (D6.1, Milestone 3). Further work has started to explore the potential to use standards for research data representation and clinical data to meet the use case requirements.

WP2 and WP4 have worked together on developing detailed scenarios for the diagnosis of chest pain, abdominal pain and shortness of breath with an evidence review that will serve as a test platform for objectives 2 and 4 throughout the project. A web-based randomized study using GPs in the UK and Greece will determine the effect of prompts and alerts on diagnostic accuracy in year 2 of the project. WP4 has started to examine the potential for standardized computable representations of clinical prediction rules.

WP5 was not active in the first year. WP7 consisted only of WT7.2, which has deployed LexEVS with a mapping between SNOMED-CT, Read and ICPC2, making this available as a TRANSFoRm project terminology service (Milestone 2).

WP8 has made some initial contacts with industry in preparation for later in the project and WP9 has been logging presentations and publications according to the agreed policy.

Description of the main results achieved so far

The following deliverables have been made available:

D1.1. Description of use cases

D3.1 Provenance model

D3.2 Report on regulatory requirements, confidentiality and data privacy issues. *This describes a model of three functional zones, data flows between zones being managed by linkers and privacy filters to ensure privacy of personal data. A paper was presented at the 2nd American Medical Informatics Association Clinical Research Informatics Summit in March 2011 and was one of the top 5 papers.*

D3.3 Security policy

D6.1 Analysis of technical structures and requirements of use of available eHR systems, data repositories, genotype repositories and cancer registries.

Expected final results and their potential impact

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.

Project logo

TRANSFoRm

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