TRANSFoRm

Translational Research and Patient Safety in Europe

# D9.1 Exploitation Strategy

QUINTILES

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# 1 TRANSFoRm Objectives

The European Union (EU) has a long-standing strategy to promote greater safety and productivity for European healthcare via advanced Information Communication Technologies (ICT). Two key agenda items are the centre of this strategy:

- Addressing the clinical research crisis:
  - Hard to identify subjects,
  - Complex, costly Case Report Forms (CRFs) with duplicate data entry,
  - Research not cost-effective in EU.

- Addressing diagnostic error:
  - 60% of litigation claims against General Practitioners (GPs)[1],
  - Failure of decision support systems for diagnosis.

TRANSFoRm recognises these specific healthcare market challenges and consequently TRANSFoRm's objective is to develop a digital infrastructure that facilitates the reuse of real-world, primary care electronic health records (eHR) data to improve both patient safety and the conduct and volume of clinical research in Europe.

Specifically, the project will drive the advanced integration of clinical practice and research data to:

- Support clinical care on diagnosis and monitoring of patients,
- Support clinical research with participant identification and evaluation of outcomes,
- Support epidemiological research with large scale phenotype-genotype association studies and follow-up on trials.

# 2 Exploitation Strategy: Objectives and Lifecycle

The TRANSFoRm software suite will be built using an open-source approach and to open standards. The definition of an underlying commercialisation concept to ensure TRANSFoRm's adoption, uptake and sustainability beyond its 5-year development phase is required.

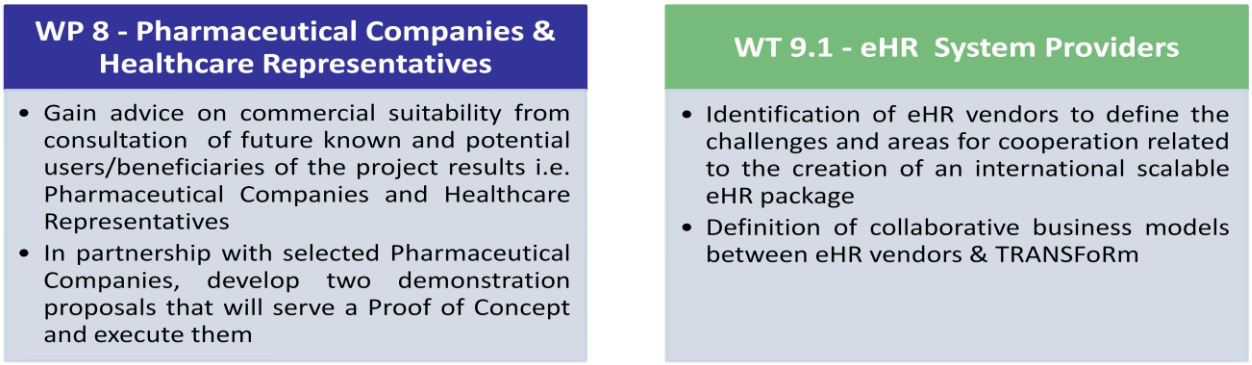
This commercialisation concept is being developed by the TRANSFoRm consortium in its Exploitation Strategy. The Exploitation Strategy incorporates the views and opinions from three key stakeholders groups regarding their needs from TRANSFoRm and its commercial suitability and will integrate potential partnering business models with electronic health record (eHR) system providers. The Exploitation Strategy thus builds primarily on the work undertaken under Work Package (WP) 8 and Work Task (WT) 9.1, activities which are being led by Quintiles.

The three key stakeholder groups with whom the consortium has engaged in the initial development of the Exploitation Strategy are:

- Pharmaceutical companies,
- Healthcare provider, payer and research organisations ("Healthcare Representatives"),
- eHR system providers,

A summary of the key activities to be undertaken with these groups is shown in **Figure 1** and explored in more detail in the section "***Stakeholder Engagement***".

**Figure 1: Summary of Activities Under WP 8 & WT 9.1**




The Exploitation Strategy will evolve over the course of the TRANSFoRm initiative and will require continuous work and collaboration from all members of the consortium. It will need to adapt concurrently with the development of the TRANSFoRm tools between Months 25 - Month 60, during which we will provide regular updates on the refinement of the Exploitation Strategy at Months 36, 48 and a final deliverable at Month 60. An overview of the key achievements for each reporting period can be found in the section "***TRANSFoRm Exploitation Strategy Roadmap: M25-M60***".

The document hereby submitted represents the current thinking regarding the Exploitation Strategy and has the following objectives:

- Present the approach in defining the Exploitation Strategy,
- Present a framework for defining sustainable business model(s) for TRANSFoRm and activities required within this,
- Provide an update on activities undertaken to-date under WP 8 & WT 9.1 within this exploitation framework,
- Share perspectives on critical success factors on which TRANSFoRm's successful exploitation is contingent upon,
- Provide an overview of the Exploitation Strategy Roadmap and next steps required.

## 3 Overview Of Our Approach

The following activities have been conducted to define the Exploitation Strategy:

- Analysis of TRANSFoRm's environment in order to understand our capabilities, customers and business environment,
- Establishment of three stakeholder user groups as defined under WP 8 & WT 9.1 and initial engagements with users,
- Development of an initial Exploitation Strategy that incorporates the initial findings from early engagement with these user groups as well as the definition of a commercialisation concept for TRANSFoRm,
- Identification of key critical success factors on which TRANSFoRm's successful exploitation is contingent upon and identification of complementary strategies to help address identified barriers,
- Definition of key next steps as part of the Exploitation Strategy Roadmap in engaging with key stakeholders and executing the proposed complementary strategies.

# 4 The Environment

## 4.1 Supra-National Innovation Forces

There are a number of issues which confound the collection of real-life healthcare data including:

- There is a lack of good quality and sufficiently representative databases in many European countries:
  - Those that exist are often incomplete within different health care centres.
  - They may be focused on the primary care or secondary care sectors, but rarely cover all the different settings and therefore do not provide a complete picture of patient care.
  - Often there are missing data or these data sets contain poorly specified or improperly coded information (e.g. on the severity of the condition).
- A further limitation is that the description of an event often differs in real-life data compared to a randomised trial.
- Finally, collection of prospective data brings its own challenges, particularly in terms of the resource effort and budget required to collect it, as well as issues in finding sources that are willing to provide the data.

Despite these issues, a compelling rationale to continue to work on observational data and real-life data before launch is that at the time of the reimbursement decision, payers are increasingly asking for more evidence of cost effectiveness that applies to real world situations rather than the controlled environment of clinical trials. Normally, this evidence is not available so the industry argues that collecting real-life data on the new drug is only possible after a decision regarding reimbursement. As a result, the majority of payers have started to accept and even request modelling. This modelling is based on the different pieces of available observational data in addition to evidence from Randomised Clinical Trials (RCTs). Some payers provide conditional approval pending the collection of real-world data collected post-launch for validation. However, this is not common practice across all countries. In those countries where modelling is not accepted or where the assumptions in the model are not accepted, reimbursement and pricing may then be negatively impacted. In consequence, it is important for the pharmaceutical industry to have a robust value package with considerable real-life evidence before launch[2].

As a result of the growing need for real-life data, many similar EU initiatives (both private and public) around the interoperability of electronic health records have been launched that aim to address these needs and drive the integration of clinical research and clinical practice (**Figure 2**). It is important to recognise that these initiatives compete for input and therefore time and resources of pharmaceutical companies. For instance, pharmaceuticals companies such as AstraZeneca and F. Hoffmann-La Roche Ltd which we approached for TRANSFoRm, are already involved in the Innovative Medicines Initiative (IMI) EHR4CR (Electronic Health Records for Clinical Research) project. The IMI is a Public-Private Partnership between EU and European Federation of Pharmaceutical Industry and Associations (EFPIA) focused in research on needs common to the pharmaceutical industry and patients at European level. Project funding will total € 2 billion over 10 years. This funding is being provided equally by the EU and large pharmaceutical companies, which is supplying its contribution in the form of resources and personnel time. These pre-existing commitments to initiatives similar to TRANSFoRm have meant that these two companies have, so far, not been interested in participating in TRANSFoRm.

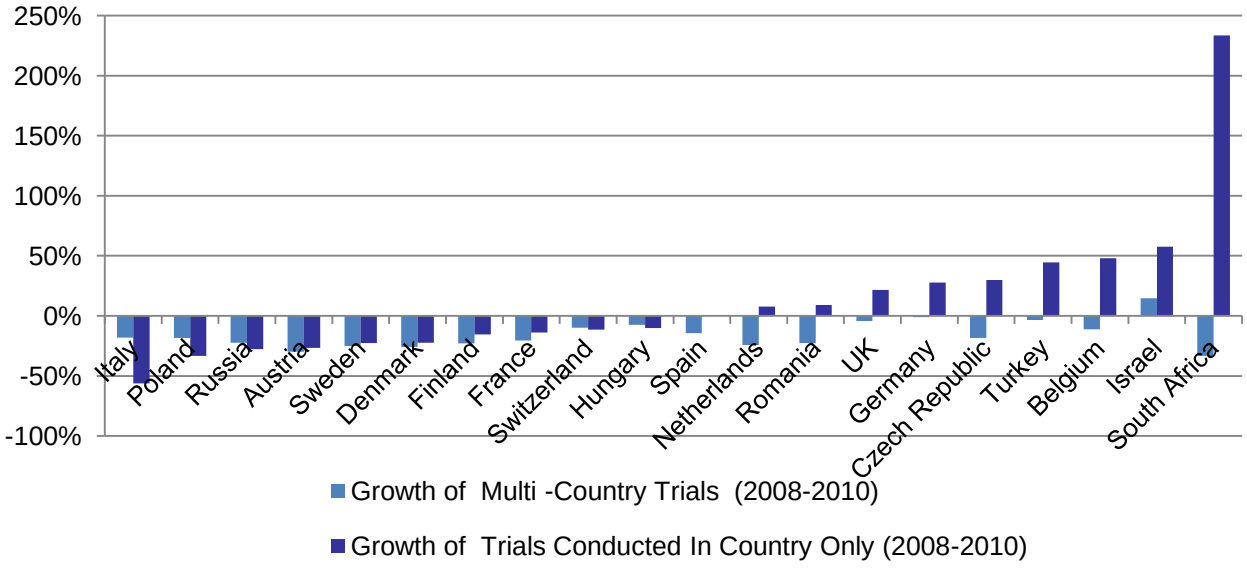
**Figure 2: Non-Exhaustive Overview Of EU Initiatives Around Interoperability Of Electronic Health Records**

| Initiatives On Re-Use of eHR | eHR Standards & Interoperability Initiatives | Longitudinal PC Databases | eHR Vendors & Strategic Data Providers |
|---|---|---|---|
| • **EU:** IMI - Europe's largest public-private partnership<br>  • **EHR4CR**: Re-use of hospital eHRs for clinical research<br>  • **EMIF**: Build of a European Medical Information Framework of patient-level data to support a wide range of medical research<br>  • ...<br>• **US:**<br>  • PACeR<br>  • ePCRN / caBIG<br>  • ... | • **IHE** promotes the coordinated use of established standards<br>• **CDSIC** develops and supports global, platform-independent data standards that enable information system interoperability<br>• **EuroRec Institute** supports, as the European authorised certification body, EHRs certification development, testing and assessment by defining functional and other criteria | • **GPRD / CPRD**:<br>  • Based on Vision provided by iNPS, a Cegedim Company<br>  • Building on the GP-only data of the GPRD, the CPRD will link data from GP and hospital care<br>• **THIN**:<br>  • Based on Vision provided by iNPS, a Cegedim Company<br>  • Unlike GPRD, no restrictions limiting it to not-for-profit activities in the public benefit<br>• ... | • **eHR Vendors**<br>  • Cegedim<br>  • Inps<br>  • EMIS<br>  • ....<br>• **Strategic Data Providers**<br>  • Cegedim CDS<br>  • IMS Health<br>  • Taylor Nelson Sofres plc<br>  • GFK<br>  • Synovate<br>  • .... |

### 4.2 National Political Forces

The productivity and yield of investment in the pharmaceutical industry has dramatically declined over the last decade: in simple terms the industry has to spend more to yield less. Efficient research is thus critical and an important criteria in the design and placement of clinical trials. As illustrated in **Figure 3,** the numbers of clinical trials conducted in Europe is on the decline and EU countries risk losing their position in clinical research, as industry looks ever more widely for attractive locations for research activity.

**Figure 3: Quintiles Analysis Of Country Attractiveness**



In response to this decline, individual countries compete to be attractive by aiming to improve trial timelines, costs and productivity as illustrated below. For instance with the Clinical Practice Research Datalink (CPRD), the UK government has launched a "world-class e-health secure research service" that will provide life science researchers with greater access to anonymised NHS patient data. Ministers argue the CPRD will help to improve public health by helping researchers to gain a better understanding of the causes of conditions like cancer and diabetes, develop new treatments for patients, and attract investment to the UK's life sciences sector.

**Table 1: Major Decision-Making Criteria For The Placement Of Clinical Research**[3]

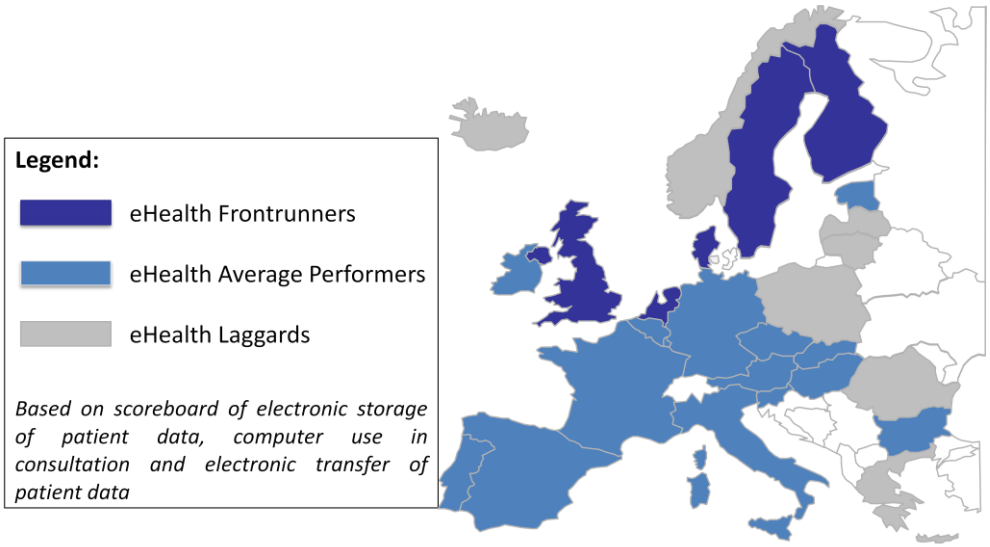
| Criterion | Importance | Key Elements |
|---|---|---|
| Strategic Relevance | High | • Value of the market opportunity<br>• Time for product to be launched and accepted in the market<br>• Degree to which key opinion leaders are needed for success |
| Quality | High | • Prevalence of desired patient or disease<br>• Availability of skills physicians and investigators<br>• Domain expertise (e.g. CNS, Oncology, specialty devices)<br>• Quality of protocol adherence<br>• Tracking and data systems |
| Time | High-Medium | • Approval time (e.g. Protocol approval time by Ethics Committee and Regulatory Agencies)<br>• Site set-up<br>• Patient enrolment time<br>• Speed of CRF completion and transmission |
| Reliability | Medium | • Ability to forecast delivery against targets<br>• Predictability of delivery against targets |
| Cost | Medium-Low | • Trial or clinical investigation cost (e.g. Investigator, site, overheads)<br>• Level of R&D tax incentives |

It is critical to recognise that in this competitive environment, pan-EU research-capabilities tools such as TRANSFoRm may be perceived either as field-levellers by individual countries pursuing national Life Science growth strategies, or as opportunities to adopt state of the art technologies as a starting point to national differentiation (as CPRD is committed to do with TRANSFoRm). However, in countries where no such efforts have been put in place, TRANSFoRm represents an opportunity to increase the efficiency of clinical research. This is a key element of the value proposition being developed to the Healthcare Representatives with whom we are engaging as part of the activities undertaken under WP 8.

### 4.3 eHR Market Dynamics

Rapid development has taken place in the eHealth area in Europe over the past five years, and GPs have been able to profit from it. A basic ICT infrastructure consisting of computers and internet connections is today available in many of the GP practices in Europe. Whilst the electronic storage of administrative and medical patient data, the use of a computer during consultation with patients and other uses of ICT in the health area are becoming more and more a daily experience in the practice, overall the use of ICT for Health purposes by GPs in Europe varies considerably [4] as illustrated in **Figure 4**.

### Figure 4: ICT Use For Health Purposed By GPs In Europe




The market of suppliers of eHR systems is highly fragmented with over 240 primary care eHR vendors in Europe and 290 systems listed by EuroRec[5] (**Table 2**). As a result of this fragmentation, we anticipate that recruitment for this user group as part of WT 9.1 will be very resource-intense and a targeting of international players will thus be essential.

### Table 2: Market Of Electronic Healthcare Record System Providers

| | **Primary Care** |
|---|---|
| Suppliers | 240 |
| Applications | 290 |
| Applications/Supplier | 1.2 |
| International Applications | 26 |
| Intern./National Applications | 8.9% |
| Countries Reported | 22 |
| Average Application/ Country | 13.1 |
| Average Supplier/Country | 10.9 |
| Average International Applications / Country | 1.1 |

## 5 Stakeholder Engagement

As part of WP 8, we have started to engage with key customers to ensure that TRANSFoRm's outputs will meet pharmaceutical companies' commercial needs for the execution of their clinical studies and healthcare organisations needs when investigating the position in therapy and clinical impact of new treatments. This early engagement provides an initial communication channel to raise awareness of TRANSFoRm tools and services in the pre-launch stage, and the activities are focused on collecting feedback from potential customers on TRANSFoRm's design and ensuring the commercial suitability of the final tools and products. This consultation represents a unique opportunity for participating companies to not only influence TRANSFoRm design but also its business model. Details of the principal activities to be undertaken with these two user groups are described in the table below.

**Table 3: Engaging TRANSFoRm Customers in TRANSFoRm Development**

<table>
<tr><th>Pharmaceutical Companies</th><th>Healthcare Representatives</th></tr>
<tr><td colspan="2">• Contribute to the review of synthesised deliverables to ensure that key user requirements have been taken into account and incorporate user feedback into the ICT development<br>• Support the development of an exploitation strategy for the project e.g. definition of complements/services enriching TRANSFoRm core product</td></tr>
<tr><td>• Partner with TRANSFoRm in developing two demonstration proposals and executing them:<br>○ Demonstration 1 - Ability to identify and select eligible patients in primary care records<br>○ Demonstration 2 - Interoperability with Clinical Trial Data Management Software to capture clinical trial data through a functional eCRF in the eHR system</td><td>• If desirable (To be discussed with Healthcare Representatives) partner with TRANSFoRm in developing a Proof of Concept and executing it e.g. support with the use case validation</td></tr>
</table>

As part of WT 9.1, we have also started to convene an eHR system provider user group to ensure that their interests and requirements will be met by the final output form TRANSFoRm. This early engagement provides an initial step to test and refine the TRANSFoRM value proposition to this stakeholder group. Details of the activities are described in the table below.

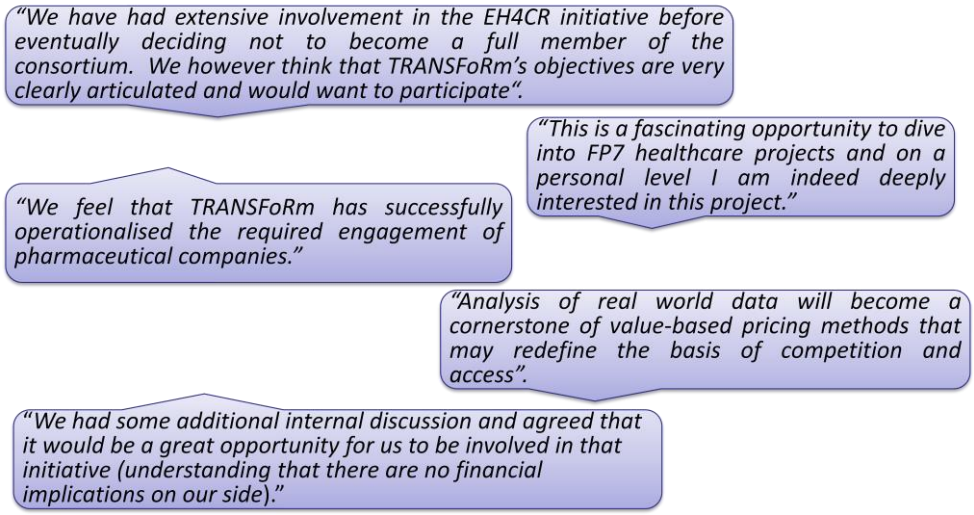
**Table 4: Engaging eHR System Providers in TRANSFoRm Development**

| eHR System Providers |
|---|
| • Define the challenges and areas for cooperation related to the creation of an internationally scalable eHR package<br>• Identify technical requirements and in particular preferred model(s) of data integration<br>• Define collaborative business models between eHR vendors & TRANSFoRm<br>• Support with the validation of the Gastro-Oesophageal Reflux Disease Use Case |

## 5.1 The Pharmaceutical Companies User Group

In spite of the complex and competitive environment discussed in an earlier section, the majority of feedback from the pharmaceutical companies approached has been positive and they acknowledge the potential benefits of TRANSFoRm. Some of their perspectives are shown in Figure 1**Figure 5.**

**Figure 5: Example Feedback From the Pharmaceutical Companies User Group**




A key objective of engagement with pharmaceutical companies is to secure participation in the demonstration cases. Consequently we targeted pharmaceutical companies with pipelines in Diabetes & Gastro-Oesophageal Reflux Disease (GORD).

**Figure 6: TRANSFoRm Pharmaceutical Companies User Group**

The next steps of the engagement with pharmaceutical companies are part of WP 8 and will include the following activities:

- Continue identification of participants. We envisage to have up to 5 pharmaceutical companies sitting on this User Group. To start with, Demonstration 1 will be planned and executed with one company only. The experience of running Demponstration 1 will inform the planning of Demonstration 2, which may then be extended to include more representation.
- Organise a workshop to conduct a deeper dive into TRANSFoRm tools and applications and gain input and feedback from pharmaceutical companies,
- Identify one pharmaceutical company to collaborate with on Demonstration 1,
- Start planning Demonstration 1.

### 5.2 The Healthcare Representatives User Group

We have contacted National and supranational bodies in Europe with an interest in conducing primary care epidemiological studies.

- The objective is to create a international healthcare users group to ensure that TRANSFoRm's outputs meets their needs when investigating the position in therapy and clinical impact of new treatments along with the planning data needed by Healthcare providers.
- The profile of healthcare users envisaged is a national level body in Europe (non-UK as we have GPRD/CPRD representation already nor Dutch as we have NIVEL representation in the Consortium) with an interest in conducing primary care epidemiological studies. The focus is on research addressing the second translational gap (clinical research / healthcare delivery) since general practice research has a key role in bridging this gap.
- TRANSFoRm's value proposition to these groups is to support epidemiology research in other EU countries where no such GPRD/NIVEL equivalent database exists and where therefore TRANSFoRm tools will facilitate the interoperability of the various dispersed databases (assuming that these are accessible through TRANSFoRm).

We have had encouraging interest from supranational bodies such as the European Medicines Agency (EMA) in Europe. However, the targeting of national bodies in Europe, others than UK & Netherlands already represented through General Practice Research Database (GPRD) / Clinical Practice Research Datalink (CPRD) & Netherlands Institute For Health Services Research (NIVEL) will require further efforts.

**Figure 7: TRANSFoRm Healthcare Representatives User Group**

As part of the process of recruitment for this user group, we have also contacted the European Forum for Primary Care (EFPC) and placed a call for participation amongst its members. The EFPC was initiated in early 2005 by a group of interested parties from several countries with the aim to improve the health of the population by promoting strong primary care. This is done by advocating for primary care, by generating data and evidence on primary care and by exchanging information between its members.

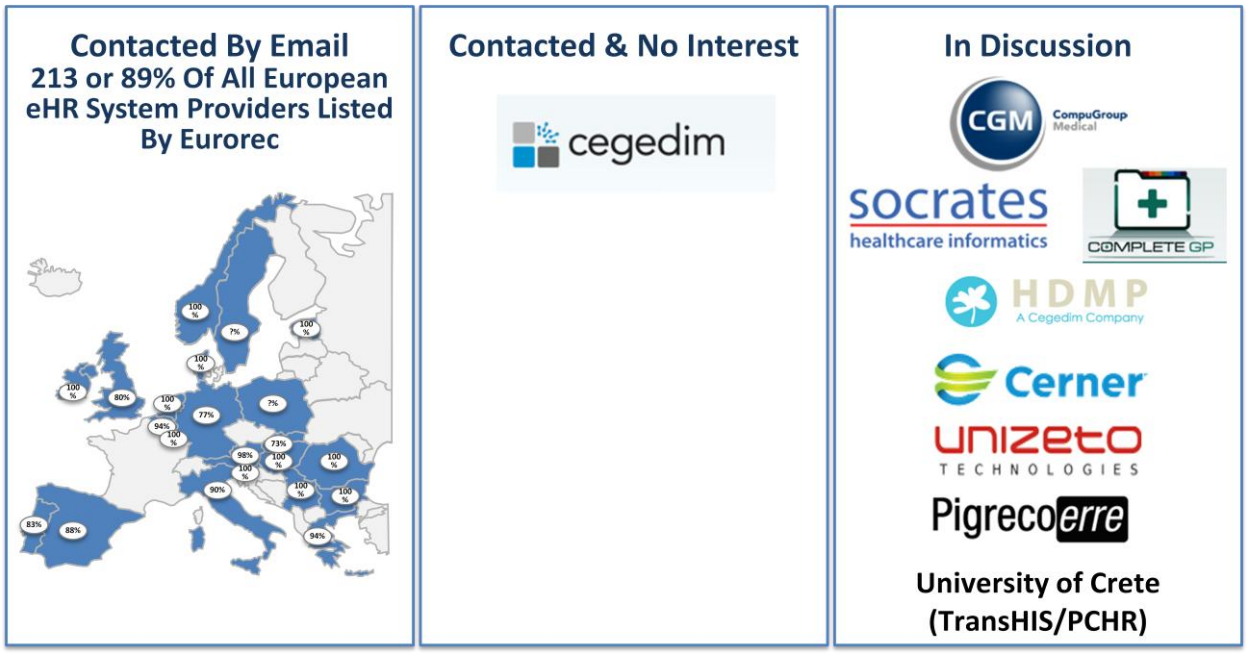
The next steps of our engagement with healthcare representatives are part of WP 8 and will include the following activities:

- Continue with the identification of healthcare contacts - National or pan-European Decision making bodies with an interest in conducing Primary Care epidemiology,
- Organise a workshop to conduct a deeper dive into TRANSFoRm tools and applications and gain input and feedback,
- Identify requirements if any to conduct a Proof of Concept e.g. support with the Use Case Validation.

### 5.3 The eHR System Providers User Group

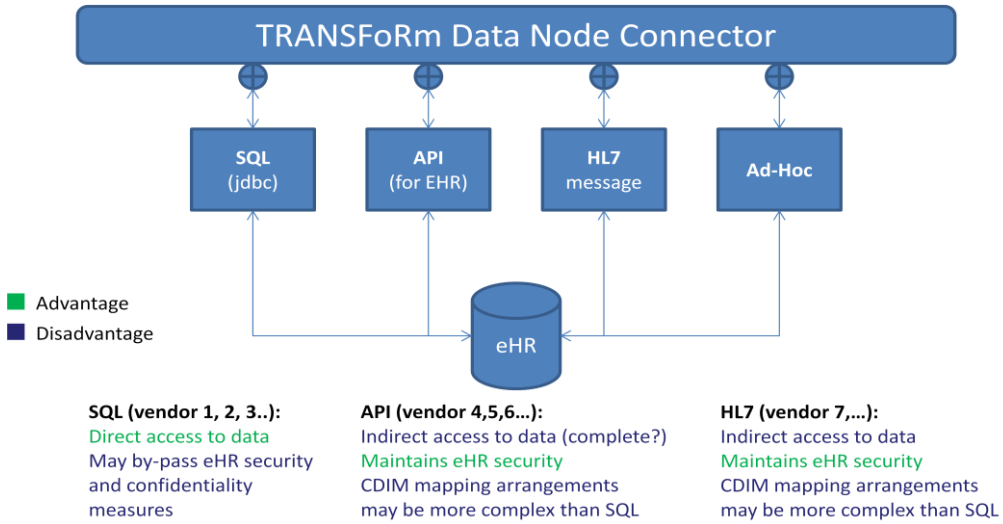
Initial engagement with the eHR system providers focused first on those that had been identified by the consortium in 2011 and had expressed an interest at the time in participating in TRANSFoRm. In addition, recognising the highly fragmented nature of the market, we also approached international players such as Cegedim, Cerner and CompuGroup.

**Figure 8: TRANSFoRm eHR System Provider User Group**




We have focused the discussions on assessing their reaction to TRANSFoRm's value proposition to them, specifically that TRANSFoRm will extend eHR systems functionalities in support of the advanced integration of clinical practice and clinical research thus allowing eHR vendors to reach more customers. During these initial discussions, different models of data integrations (see **Figure 9**) have also been presented to the eHR system providers, with direct access to the database being the preferred option.

**Figure 9: Alternative TRANSFoRm Models Of Data Integrations**




The next steps of engagement with eHR system providers are part of WT 9.1 and will include the following activities:

- Conduct deeper-dives into TRANSFoRm tools & applications including exploration of the data source, the data itself and the potential for linkage or achieving semantic interoperability between data sources,
- Discuss participation in Gastro-Oesophageal Reflux Disease (GORD) use case (in collaboration with Karolinska Institutet),
- Partner with eHR vendors to define communication strategies with current customers with respect to collaboration with TRANSFoRm.

# 6 TRANSFoRm Exploitation Strategy: Defining a Commercialisation Concept

## 6.1 Context

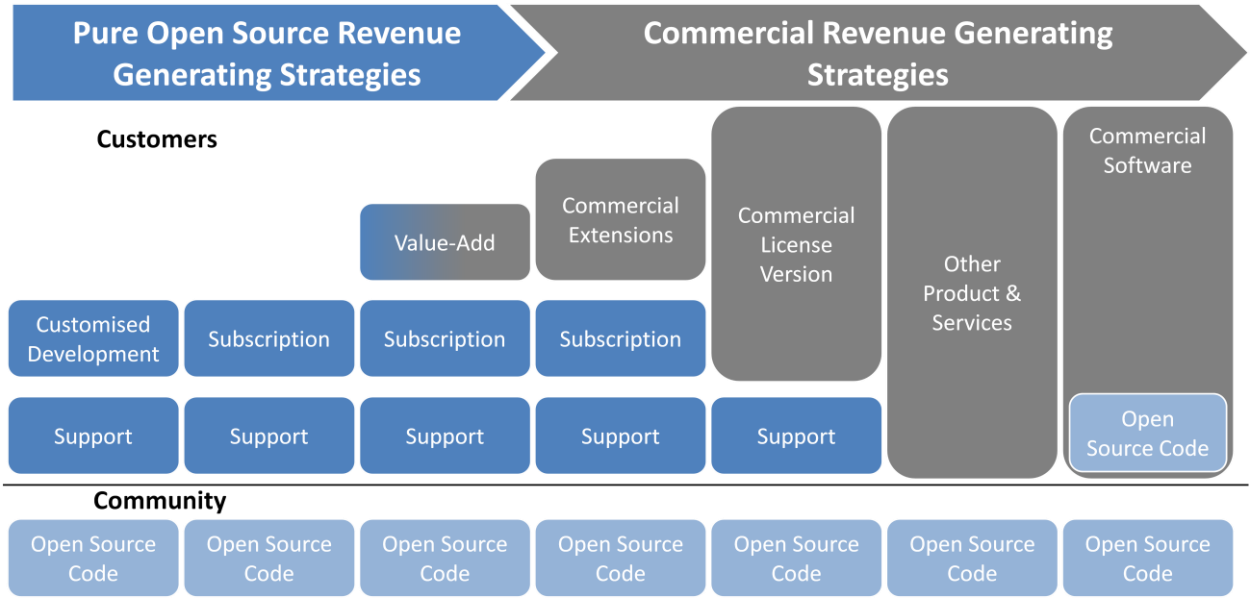
The TRANSFoRm approach is to utilise relevant open-source softwares and standards, to contribute to the development of these softwares and standards, and to use a modular approach to provide maximum integration with existing (but incomplete) solutions at both EU and international level.

Open source is not a business model itself, but a development and distribution model enabled by a licensing tactic. It does provide the opportunity for vendors to benefit from a collaborative development process, or at least provide transparency into the development process.

There are a variety of choices that can be made related to license, development models, licensing strategies and revenue triggers that combine to produce the overall business model for a specific product. Most of the combined licensing and revenue strategies can be separated into two major categories [6] (**Figure 10**):

- Pure Open Source
- Commercial Open Source

**Figure 10: Open Source Strategies**

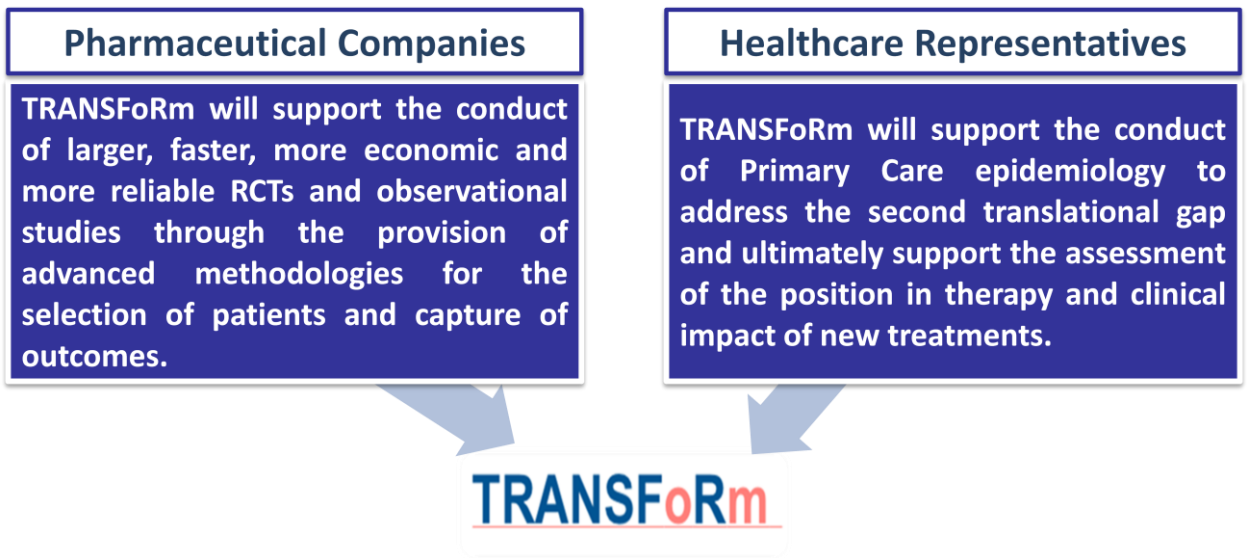



As TRANSFoRm will pursue an open-source approach and to open standards, we will seek to disseminate and integrate the products of the project with national and regional programmes and within the ICT-health industry, rather than to commercialise the project outputs directly. This approach however requires the definition of an underlying commercialisation concept to ensure TRANSFoRm's adoption, uptake and sustainability beyond its 5-year development phase.

## 6.2 TRANSFoRm Anticipated Benefits and Value Proposition

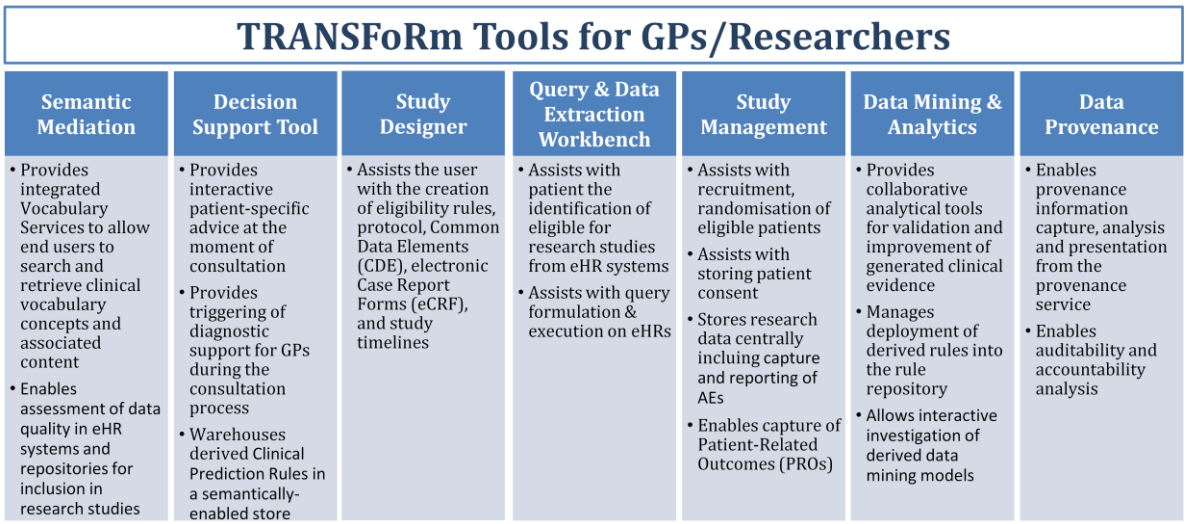
The high-level value proposition to the two major customer groups, pharmaceutical companies and healthcare representatives is illustrated in the schematic below:

**Figure 11: TRANSFoRm Key Customers**



Realisation of these value propositions will require TRANSFoRm to extend eHR systems functionalities in support of the advanced integration of clinical practice and clinical research. The extended functionalities proposed through TRANSFoRm are illustrated in **Figure 12** below.

**Figure 12: Overview of TRANSFoRm Tools**



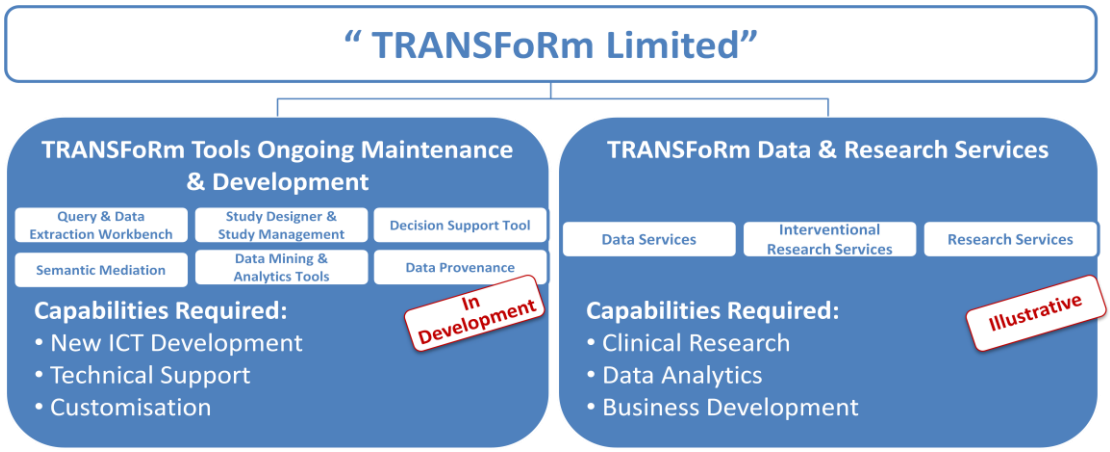

These extended functionalities will provide several benefits:

- **Support quicker and more economic recruitment and follow-up of Randomised Clinical Trials** with an integrated eHR interface that enables the rich capture of clinical data, including symptoms and signs and a query workbench that supports the identification of patient eligible to participate in clinical trials,
- **Improve patient safety** by offering a **diagnosis support tool that** will provide patient-specific advice at the moment of consultation,
- **Support large scale phenotype-genotype association studies and follow-up on trials** through interoperability of distributed eHR data and clinical data repositories that maintain provenance, confidentiality and security,
- **Drive the integration and re-use of clinical data stored in different eHR systems** with software tools and web-services that support clinical research by enabling use of controlled vocabulary and standardised data elements,
- **Enhance uptake of eHR systems that offer support for clinical care and research** by allowing eHR vendors and data integrators to reach more customers.

### 6.3 TRANSFoRm "Limited"

To bring this value proposition to the users, TRANSFoRm will need to adopt a commercial open source model whereby revenues are generated by selling value-add TRANSFoRm services to customers such as pharmaceutical companies and healthcare provider and payer organisations. In support of this approach, we recommend the establishment of a "TRANSFoRm Limited" organisational model centred around key capabilities as described below. This will serve as the umbrella organisation that manages the continuous development and maintenance of TRANSFoRm tools but also the provision of data and research services leveraging these tools. Going forward, we will engage with the consortium members to identify key players in this model and in particular organisations that are interested in becoming service-providers.

**Figure 13: TRANSFoRm Commercialisation Concept**




We will work with the identified organisations to define complimentary services that are revenue-generating to sustain the project in the long run. Examples that illustrate the kind of services that can be envisaged for TRANSFoRm and an example of a research service are provided below:

**Example 1 - Possible Service Offerings: CPRD provides capability, products and services across three areas**

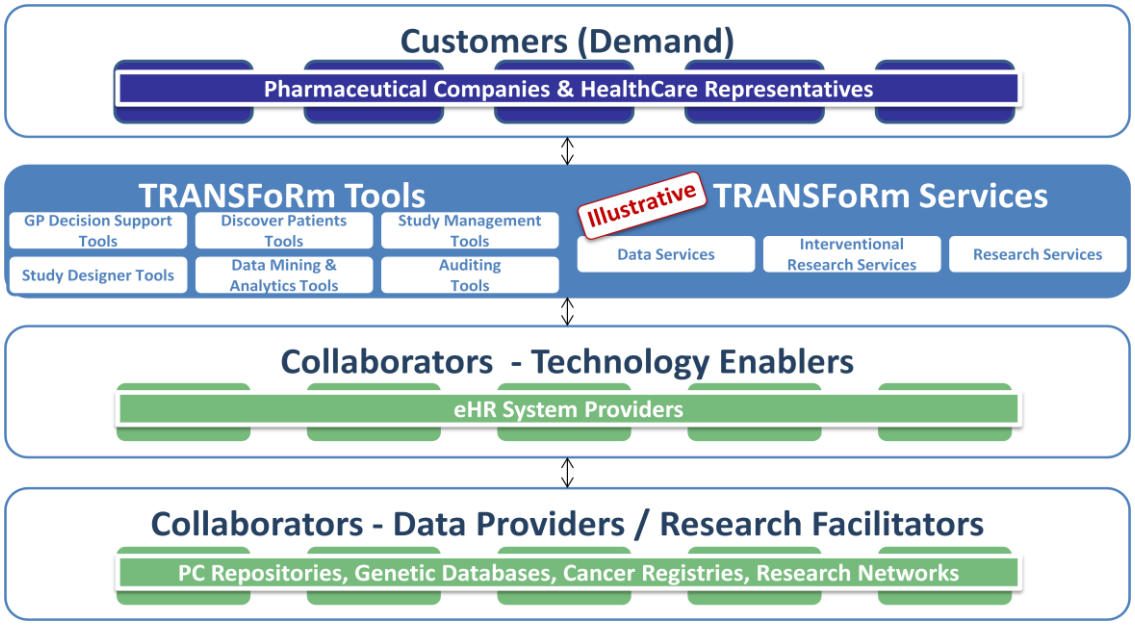
- **Data Services:** access to data for researchers (NHS, social care and others); data matching and linkage services, data validation and access to real time data to facilitate surveillance activities and support the public health agenda.
- **Interventional Research Services**: feasibility of research proposal (i.e. are there enough research subjects in a given area to provide a meaningful research result?); site and patient level recruitment; full electronic-data (e-data) services; Linkage services for clinical trials, full clinical trial input; biological sample collection and linkage; patient reported outcomes collection and linkage
- **Research Services:** advise on research methodology, research governance and feasibility of research proposals; provide consultancy services including the provision of patient and / or healthcare professional input; ability to undertake research studies on behalf of customers.

**Example 2 – Research Service: Quintiles' experience of a hybrid observational study combining eHR data and prospective data collection in Primary Care settings**

- Assess practice patterns, patient experiences, and outcomes in the management of type 2 Diabetes patients: A Diabetes Practice Based Research Network (DPBRN)
- Planned 9,000 patients across 300 sites in North America
- Initial eHR system is Greenway; others to be added
- Leveraging existing eHRs allows for:
    - More sophisticated site and patient sampling
    - Ongoing passive data collection
    - Less data collection burden on busy sites
    - Retrospective 1-year look-back period appended to 3-year prospective follow-up period
- Foundation Study plus Two Sub-studies
- Focus on injectables, referral dynamics

**Figure 14** below provides a diagrammatic representation of how the tools and services that will be developed in the TRANSFoRm initiative will link the demand from the customers to the underlying data through the technology collaborators, principally the eHR system providers.

Figure 14: TRANSFoRm Exploitation Strategy Framework




## 7 Critical Success Factors

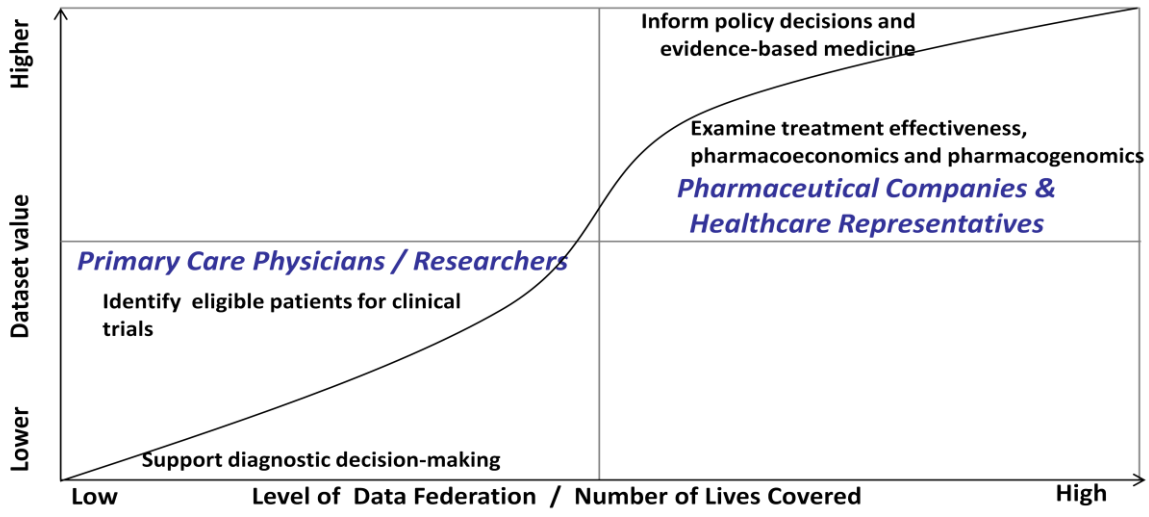
TRANSFoRm's successful exploitation is contingent upon several critical success factors that have been identified and clarified through the initial discussions with the three user groups:

- Providing adequate data coverage to support the needs of customers,
- Defining complementary strategies to establishing partnerships with eHR system providers.

### 7.1 Providing Adequate Data Coverage to Support the Needs of Customers

The value of the datasets is intrinsically linked to the coverage of patients. Customers such as pharmaceutical companies and national or supranational bodies with an interest in conducing primary care epidemiology studies to address the second translational gap, require access to extensive data sets to support their needs.

Figure 15: TRANSFoRm Data Value



This data volume consideration will require the establishment of a centralised communication strategy to strengthen the engagement of Data Providers and Research Facilitators with TRANSFoRm and thereby increase its coverage of patients. Different level of engagements will apply depending on the profile of the Research Network & Data Repositories as show in the table below.

**Table 5: Communication Strategy To Strengthen The Engagement Of Data Providers And Research Facilitators**

| | Profile | Level Of Engagement | Responsibility |
|---|---|---|---|
| 1 | Research Networks / Data Repositories involved in the use case validation | **Active Engagement:**<br>• Direct communication<br>• Active involvement/collaboration with the use case validation | WP 1 Led by the University of Antwerp supported by all WPs as required |
| 2 | Research Networks / Data Repositories who agreed to participate and who are not involved in the use case validation because of lack of readiness | **Maintain Active Communication:**<br>• TRANSFoRm Newsletter<br>• Personalised introduction call with focus on TRANSFoRm benefits & tools | **Centralised Project Management** with support from all WPs as required |
| 3 | Other Research Networks / Data Repositories contacted in WT1.2 or WT6.1 and 6.2 (Tirre)- or who contacted TRANSFoRm<br>+ International networks: EGPRN, PCDE, ESPCG, WONCA | **Increase Awareness:**<br>• TRANSFoRm Newsletter<br>• Presentations at conferences | **Centralised Project Management** with support from all WPs as required |

### 7.2 Defining Complementary Strategies to Establishing Partnerships With eHR System Providers

Partnership with eHR system providers is critical in allowing TRANSFoRm to extend their standard eHR systems functionalities to support the advanced integration of clinical practice and clinical research. However, as described earlier this is a highly fragmented market and consequently recruitment for this user group is very resource-intense and modest progress has been made to date in engaging with these vendors, so the next steps will involve complementing the current efforts with the following strategies:

- ***Further strengthen the value proposition to eHR system providers***

***From:***

---

- Saving on development cost by instead adopting TRANSFoRM open source software
- Enhancing the adoption of eHR systems by providing an easier, more accurate, and faster means of entering data
- Allowing to reach more customers

***To:***

---

- Moving from today's walled garden eHR platforms towards agile development of collaborative platform solutions
- Becoming a frontrunner of eHR market growth and evolution
- Entering an adjacent market whereby data aggregation is monetised and customers include among others pharmaceutical companies

- ***Prioritise the engagement of eHR system providers***

Recognising the highly fragmented nature of the market, we would recommend a multi pronged strategy based on the country stratification. The groupings below are a starting point and will require further country-level analysis:

- Group 1: Matured and centralised access point eHR (e.g. UK, France, Estonia, Sweden)
- Group 2: Federated but consistent Ehr (e.g. Turkey)
- Group 3: Fragmented and multiple players (e.g. Germany)
- Group 4: Limited eHR in country

- ***Create a critical groundswell of demand from GPs for extended eHR functionalities through a combined top-down and bottom-up approach.***

In addition to the current efforts on defining strict and open standards and certification of eHR softwares, we will explore the benefits of potential European incentives (financial or non-financial) to encourage physicians to adopt extended eHR functionalities such as these provided by TRANSFoRm. An example of such financial incentives that has been very successful in encouraging adoption of interoperable eHR technologies is the Health Information Technology for Economic and Clinical Health (HITECH) Act in the US.

***The HITECH Act set meaningful use of interoperable eHR adoption in the health care system as a critical national goal and incentivised eHR adoption.***

- The HITECH Act, part of the American Recovery and Reinvestment Act of 2009 (ARRA), allocates $19.2 billion in the form of direct payments to physicians and hospitals in order increase the use of eHRs.
- The stick: Doctors who do not adopt an eHR by 2015 will be penalized 1% of Medicare payments, increasing to 3% over 3 years. .
- The carrot: Doctors and other eligible professionals can qualify for incentive payments totalling as much as $44,000 through Medicare or $63,750 through Medicaid. Hospitals can qualify for incentive payments totalling some $2 million or more. In order to receive the EHR stimulus money, the HITECH act (ARRA) requires doctors to show "meaningful use" of an EHR system
- By 2014, electronic health records should be nearly universal, according to the Obama administration.

Another approach we believe it is important to now consider to encourage the adoption of TRANSFoRM compatible eHR system and thereby stimulate bottom-up demand for participation of eHR vendors in TRANSFoRm, is to revise the current description of work to include the definition of awareness and advocacy campaign centred around clear articulation of TRANSFoRm's benefits to primary care physicians as shown below.

**Table 6: TRANSFoRm Value Proposition to Primary Care Physicians**

| Diagnostic Decision Support - Improving Patient Safety | Clinical-Research Capabilities in General Practice - A significant Income Enhancer |
|---|---|
| • GPs as gatekeepers (90% of consultation) of the healthcare system under pressure to reduce 'unnecessary' investigations and referrals while required to detect serious conditions early on – but not always successful<br>• Previous attempts to develop decision support systems for diagnosis largely ineffective mostly because not embedded directly with eHR system | • Primary care-based trials requiring substantial investments in time and resources<br>• Lack of technological solutions to provide easier, more accurate, and faster means of capturing data and avoiding double data entry between the eHR system and the Case Report Form |
| **Value Proposition:** TRANSFoRm Decision Support Tool will provide patient-specific advice at the moment of consultation so that clinicians are able to access and quantify likely differential diagnoses framed in terms of diagnostic probability and alternative diagnostic possibilities. | **Value Proposition:** TRANSFoRm Clinical-Research Capabilities will provide GPs with easier and faster means to extend their participation in clinical research and further benefit from investigator fees. |

## 8 TRANSFoRm Exploitation Strategy Roadmap: M25-M60

Based on this review of current progress on WP 8 & WT 9.1 and in light of the critical success factors highlighted above, we have defined the Exploitation Strategy Roadmap for TRANSFoRm for months 25-60. This is summarised in the schematic diagram below.

**Legend:**

Customers - Pharmaceutical Companies

Customers - Healthcare Representatives

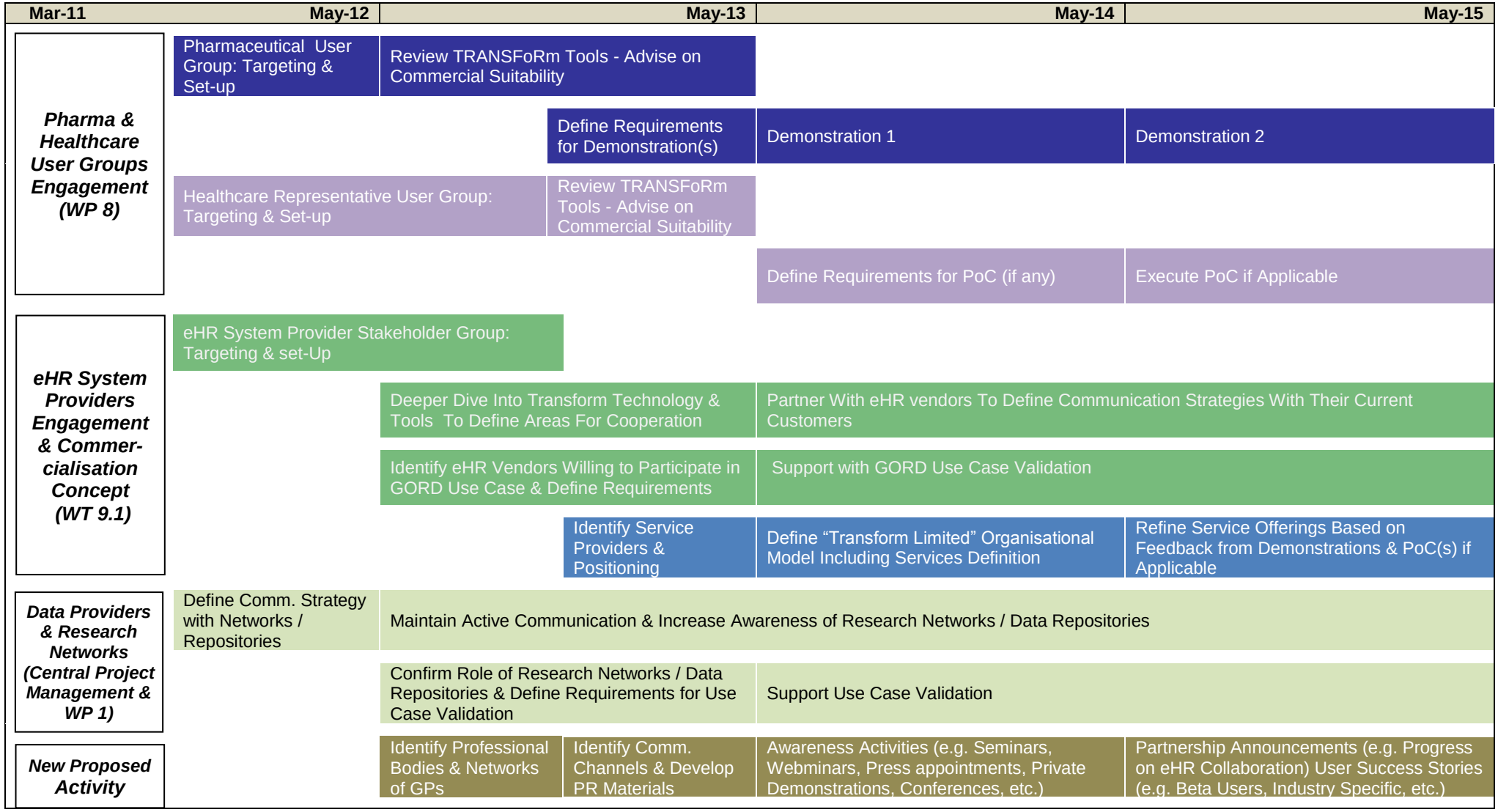
Collaborators - eHR System Providers

Collaborators - Data Providers / Research Facilitators

Lobbying Power - Bodies /Networks of General Practitioners

TRANSFoRm Capabilities

**Figure 16: TRANSFoRm Exploitation Strategy Roadmap**



The definition of the Exploitation Strategy will require continuous work and will need to evolve at the same pace as the development of TRANSFoRm tools between Month 25- Month 60, a period during which we will provide regular updates at Month 36, 48 and a final deliverable at Month 60.

**Table 7: Exploitation Strategy Roadmap Key Deliverables.**

| Reporting Period | Key Deliverables | Responsible |
|---|---|---|
| **Month 24** | • Exploitation Strategy Framework including:<br>  ○ Update on WP 8 & WT 9.1 - Engaging Key Stakeholders:Pharmaceutical Companies,Healthcare Representatives, eHR System Providers<br>  ○ Early Commercialisation Concept<br>  ○ Critical Success Factors<br>  ○ High-Level Exploitation Strategy Plan | • Quintiles |
| **Month 36** | • Consolidated Feedback On Commercial Suitability From Pharmaceutical Companies and Healthcare Representatives<br>• Demonstration(s) Planning | • Quintiles<br>• Quintiles |
| | • Report on eHR Engagement and Defined eHR Areas of Cooperation<br>• Requirements for eHR Support with GORD Use Case Validation<br>• Potential TRANSFoRm Value-Add Service Providers & Positioning | • Quintiles with input from ICT Developers<br>• Input from Karolinska Institutet<br>• Quintiles with input from all consortium members |
| | • Update on Communication Activities with Research Networks / Data Repositories (To be provided by TRANSFoRm Central Project Management)<br>• Confirmed Role of Research Networks / Data Repositories & Define Requirements for Use Case Validation (To be provided as part of the update D10.3 - Protocol For Final Validation) | • Centralised Project Management<br>• WP 1 Led by The University of Antwerp |
| | • Overview of Primary Care awareness and advocay campaign | • TBD |
| **Month 48** | • Report on Demonstration 1<br>• PoC Requirements If Any (e.g. Participation in Use Case Validation) from Healthcare Representatives | • Quintiles<br>• Quintiles |
| | • Update on eHR Collaboration & Communication Strategies<br>• Update on eHR Support with GORD Use Case Validation (To be presented as an update on delivery of D1.3 Final Validation Of The Feasibility Of Transform To Deliver The GORD RCT)<br>• Transform Limited" Organisational Model Including Services Definition | • Quintiles with input from ICT Developers<br>• Input from Karolinska Institutet<br>• Quintiles with input from all consortium members |

| Reporting Period | Key Deliverables | Responsible |
|---|---|---|
| | • Update on Communication Activities with Research Networks / Data Repositories (To be provided by TRANSFoRm Central Project Management)<br>• Update on Research Networks / Data Repositories Support with Use Cases Validation (To be provided as part of the update on delivery of D1.2 Final Validation Of The Feasibility Of Transform To Deliver The Genotype-Phenotype Study & D1.3 Final Validation Of The Feasibility Of Transform To Deliver The GORD RCT) | • Centralised Project Management<br>• WP 1 Led by The University of Antwerp |
| | • Report on GP PR Awaress Activities | • TBD |
| **Month 60** | • Report on Demonstration 2<br>• Report on PoC Execution with Healthcare Representatives If Applicable | • Quintiles<br>• Quintiles |
| | • Update on Communication Activities with Research Networks / Data Repositories (To be provided by TRANSFoRm Central Project Management)<br>• Update on Research Networks / Data Repositories Support with Use Cases Validation (To be presented under D1.2 Final Validation Of The Feasibility Of Transform To Deliver The Genotype-Phenotype Study & D1.3 Final Validation Of The Feasibility Of Transform To Deliver The GORD RCT) | • Centralised Project Management<br>• WP 1 Led by The University of Antwerp |
| | • Report on eHR Support with GORD Use Case Validation (To be presented under D1.3 Final Validation Of The Feasibility Of Transform To Deliver The GORD RCT)<br>• Overview of Services For Pharmaceutical Companies & Healthcare Representatives | • Input from Karolinska Institutet<br>• Quintiles with input from all consortium members |
| | • Report on GP PR Annoucements | • TBD |

# 9 Summary and Conclusions

TRANSFoRm recognises today's specific healthcare market challenges and consequently TRANSFoRm's objective is to develop a digital infrastructure that facilitates the reuse of real-world, primary care electronic health records (eHR) data to improve both patient safety and the conduct and volume of clinical research in Europe.

As the TRANSFoRm software suite will be built using an open-source approach and to open standards, the definition of an underlying commercialisation concept to ensure TRANSFoRm's adoption, uptake and sustainability beyond its 5-year development phase is required. This commercialisation concept is being developed by the TRANSFoRm consortium in its Exploitation Strategy. The Exploitation Strategy incorporates the views and opinions from three key stakeholders groups regarding their needs from TRANSFoRm and its commercial suitability and will integrate potential partnering business models with electronic health record (eHR) system providers. The Exploitation Strategy thus builds primarily on the work undertaken under Work Package (WP) 8 and Work Task (WT) 9.1, activities which are being led by Quintiles.

To define the Exploitation Strategy, we conducted the following activities:

- We performed an environmental analysis of TRANSFoRm's environment in order to understand our capabilities, customers and business environment.
- We started establishing the three stakeholder user groups as defined under WP 8 & WT 9.1 and had initial engagements with users.
- We developed an Exploitation Strategy that incorporates the initial findings from early engagement with these user groups as well as the definition of a commercialisation concept for TRANSFoRm.
- While engaging with key stakeholders, we also identified key critical success factors on which TRANSFoRm's successful exploitation is contingent upon and identify complementary strategies to help address identified barriers.
- We defined key next steps as part of the Exploitation Strategy Roadmap in engaging with key stakeholders and executing the proposed complementary strategies.

This approach has informed our view of TRANSFoRm's commercial success and the need for adopting a commercial open source model whereby revenues are generated by selling value-add TRANSFoRm services to pharmaceutical companies and healthcare representatives. As such, we recommend the establishment of a "TRANSFoRm Limited" organisational model centred around key capabilities. This will serve as the umbrella organisation that manages the continuous development and maintenance of TRANSFoRm tools but also the provision of data and research services leveraging these tools. Going forward we will engage with the consortium members to identify key players in this model and in particular organisations that are interested in becoming service-providers.

While engaging with key stakeholders over the last six months, we have also identified several key critical success factors on which TRANSFoRm's successful exploitation is contingent upon and identify complementary strategies to help address identified barriers. First, the value of the datasets is intrinsically linked to the coverage of patients. Customers such as pharmaceutical companies and national or supranational bodies with an interest in conducing Primary Care epidemiology to address the second translational gap will require access to extensive data sets to support their needs. This data volume consideration will require the establishment of a centralised communication strategy to strengthen the engagement of Data Providers and Research Facilitators. Different level of engagements will apply depending on the profile of the Research Network & Data Repositories. Secondly, in light of the challenges encountered with the setting up of the eHR system provider user group, we think it would be critical to define complementary strategies. We would recommend creating a critical mass of demand and advocacy from primary care physicians for extended eHR functionalities through a combined top-down and bottom-up approach of European incentives and campaigns targeting GPs professional bodies and networks. The latter would require revision of the current Description of Work.

Finally, the definition of the Exploitation Strategy will require continuous work and collaboration from all members of the consortium as described in the section "***TRANSFoRm Exploitation Strategy Roadmap: M25-M60***". It will need to evolve at the same pace as the development of the TRANSFoRm tools between Month 25 - Month 60, a period during which we will provide regular updates at Month 36, 48 and a final deliverable at Month 60.

## 10 References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## 11 Abbreviations

CPRD: Clinical Practice Research Datalink

DDS: Diagnostic Decision Support

eCRF: Electronic Case Report Form

EHR4CR: Electronic Health Records for Clinical Research

eHR: Electronic Health Care Record

EU: European Union

EMA: European Medicines Agency

EFPIA: European Federation of Pharmaceutical Industry and Associations

GORD: Gastro-Oesophageal Reflux Disease

GP: General Practitioners

GPRD: General Practice Research Database

HITECH: Health Information Technology for Economic and Clinical Health

ICT: Information Communication & Technologies

IMI: Innovative Medicines Initiative

NIVEL: Netherlands Institute For Health Services Research

RCTs: Randomised Clinical Trials

WP: Work Package

WT: Work Task