# D9.3 Final Exploitation Plan

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Objectives

The exploitation plan builds upon the initial D9.1 Exploitation Strategy\(^1\) submitted by Quintiles in 2012, and should be read as an update on the implementation of that strategy. The exploitation plan is focused on exploitation efforts and business model definition. The original objectives are listed below:

- Identification of electronic health record (EHR) vendors to define the challenges and areas for cooperation, which have been outlined in the SWOT analysis below
- Identification of business models to exploit open-source software additions
- Creation and maintenance of a TRANSFoRm exploitation strategy

Report structure

Table 1. below outlines the structure of the D9.3 Final exploitation plan report.

Table 1. Structure of D9.3 Final exploitation plan report

<table>
<thead>
<tr>
<th>#</th>
<th>Objective</th>
<th>Contributing Section</th>
</tr>
</thead>
</table>
| 1  | Identification of EHR vendors to define the challenges and areas for cooperation, which have been outlined in the SWOT analysis below | • Stakeholder engagement  
• Critical success factors  
• SWOT analysis |
| 2  | Identification of business models to exploit open-source software additions | • Context for TRANSFoRm 'Limited'  
• The business model |
| 3  | Creation and maintenance of a TRANSFoRm exploitation strategy               | • Organizational framework  
• Strategies for TRANSFoRm |
Stakeholder engagement

The initial stakeholder engagement resulted in limited responsiveness from stakeholders despite the exploitation strategy roadmap. An initial stakeholder engagement strategy conducted by Quintiles which was submitted in 2012\(^1\). National bodies from Germany (Institute for Quality and Efficiency in Health Care - IQWiG) and France (French health authority - HAS) showed no interest. The same was reported for pharmaceutical manufacturers AstraZeneca and Roche. Other manufacturers (Lilly, Merck, BMS) participated in a TRANSFoRm introduction workshop.
Critical success factors

Initial discussions with the three user groups identified critical success factors for the successful exploitation of TRANSFoRm. These were firstly, providing adequate data coverage to support the needs of customers and secondly, defining complementary strategies to establishing partnerships with EHR system providers. These are described in further detail bellow. Furthermore we considered a range of other Health ICT service providers and their role in the LHS.

1) Providing adequate data coverage to support the needs of customers

The value of the datasets continues to be intrinsically linked to the level of patient coverage and the quality of the data available. Prospective customers such as pharmaceutical manufactures and national bodies that express an interest in the execution of primary care epidemiology studies will require access to data sets of sufficient quality to support their needs. Primary care physicians or researchers require data sets to efficiently identify eligible patients for clinical trials whereas national bodies or pharmaceutical manufacturers require targeted data coverage for the purposes of informing policy decisions for evidence-based medicine. This is a key component in the uptake of pharmacoconomics to support reimbursement decision-making and a cornerstone of a Learning Health System. The considerable issues around Data Privacy, Security and the role of Trusted Third Parties has been discussed in D3.2 and 3.3, whilst quality is discussed in D5.1.

2) Defining complementary strategies to establishing partnerships with EHR system providers

Based upon the results of the initial stakeholder engagement it is apparent that the EHR vendor market is a highly fragmented market and consequently recruitment for this user group is very resource-intensive. TRANSFoRm formed partnerships with five EHR system providers in order to support and advance the integration of clinical practice and clinical research. An additional two vendors were unable to take part after first indicating a willingness to do so, one for strategic reasons and another on account of delays in completion of their own system.
3) Other ICT service providers

There is a growing market place for data aggregators, providers of analyses and reports for healthcare and commissioning, trusted third parties (TTP) and providers of decision support systems (DSS). TRANSFoRm has engaged with TTP’s attached to data repositories. Although initially many data aggregators and DSS saw TRANSFoRm as a threat, there has been a growing recognition that an academically-led project working with standards and innovating in the area can bring value to commercial entities.
SWOT Analysis

Figure 1. below is a SWOT analysis that refers specifically to TRANSFoRm’s strengths, weaknesses, opportunities and threats with respect to exploitation activities.

**Figure 1. SWOT analysis (strengths, weaknesses, opportunities and threats) of the exploitation activities.**

| Strengths | • RCT Demonstrated compatibility with commercially available software through Demo 2  
|           | • RCT Fist successful example of a distributed, multi-vendor e-Source solution for clinical trials  
|           | • Databases: query and data extraction possible  
|           | • DSS: Prototype shows significant benefits in evaluation  
|           | • Academic background demonstrates commitment to open-source collaboration and less of threat to commercial vendors  
|           | • Collaboration with standards organisations (CDISC) commencing  
| Weaknesses | • Limited resources to establish full commercial capabilities, e.g. Product Development, Marketing, Sales, Finance on its own  
|           | • TRANSFoRm deliverables are not all full products that can be commercialised immediately  
|           |   o The genotype-phenotype workbench depends on the availability of linked data.  
|           |   o The TRANSFoRm RCT Study system is a modular system but relies on editing CDISC ODM forms and writing structured EHR queries. Although commercial ODM editors are available, the xml needs to be edited to work with TRANSFoRm.  
|           |   o The DSS is a prototype and requires further development.  

### Opportunities
- Merge with other similar projects to provide broader portfolio of available components that could be leveraged
- Develop additional use cases to attract attention from EHR vendors, e.g. Demo 2 use case
- Founding of European Institute for Innovation Through Health Data is a suitable umbrella entity
- Add TRANSFoRm tools to CDISC portfolio and integrate with developing new standards such as ODM 2.0

### Threats
- Overlap with similar projects or commercial vendors could lead to competitive situation or confusion
- Lack of EU funding post project could damage re-use of project results.
Context for TRANSFoRm

The approach to implementing the strategy proposed in the original D9.1 Exploitation Strategy, holds to the same objectives, but has fundamentally changed in approach with the founding of the European Institute for Innovation Through Health Data. The I–HD acts as the avenue for offering a variety of project outputs under one ‘roof’ aligned with both certification capability (via EuroReC) and commercial support services (via Custodix). We will use an open source software licence arrangement to provide TRANSFoRm deliverables as software components in collaborative efforts in combination with advisory services and custom development of previously developed components. This strategy will provide the opportunity for vendors to benefit from a collaborative development process, with a strong and able partner without the threat of direct competition, which was raised as a concern for example by the company Merge which supported efforts in Demonstration 2 (D3).

In order to bring this value proposition to the users, TRANSFoRm will adopt a business model where software is provided under an open-source license, a legal entity, either the coordinator, or I–HD holding and protecting the intellectual property. TRANSFoRm keeps its not-for-profit motive, however revenues will be generated by providing value-add TRANSFoRm services to customers such as pharmaceutical companies and healthcare provider and payer organisations. Thereby, contributing to the future resourcing through such services, which fall into two broad categories:

1. Advisory services how to integrate TRANSFoRm deliverables as software components into customers’ commercial applications
2. Further software development of TRANSFoRm deliverables that customers can then integrate into their commercial applications

In support of this approach, the original recommendation stands, with the establishment of a TRANSFoRm organisational model centred around key capabilities of consortium members. TRANSFoRm management will serve as an organisational umbrella that both oversees the continuous development and maintenance of TRANSFoRm tools and also the provision of data and research services leveraging these tools.

Since the original model, TRANSFoRm has held discussions with other European entities and projects, such as EHR4CR and EuroRec, facing similar issues. We decided early on that a proliferation of ‘successor project institutes’ is highly undesirable and would be confusing for the market and European science. We supported the formation of the European Institute for Innovation Through Health Data (http://www.i-hd.eu), which offers the opportunity (which
TRANSFoRm will take up) to avoid duplication of effort and offer a wider range of software solutions. In addition TRANSFoRm is contributing to standards development with CDISC and more widely contributing to international efforts to scope and provide a maturity model for the Learning Health System.

I~HD has been founded via the IMI project EHR4CR, within which a number of TRANSFoRm partners also participated. I~HD is a legal entity, incorporated under Belgian law, its objectives are shown below (Box). Membership of I~HD will be open in the next month and TRANSFoRm will join at this point. Discussions will take place at that point as to the software, models, methods and tools that will be made available via I~HD, and whether the co-ordinator or I~HD will maintain the IP rights.
Vision of I-HD

To become the European organization of reference for guiding and catalyzing the best, most efficient and trustworthy uses of health data and interoperability, for optimizing health and knowledge discovery.

Mission

To enable, coordinate, and accelerate the efficient development and deployment of interoperable and seamless eHealth solutions and research strategies, towards achieving best practices and sustainable integrated person-centred health care, to optimize health and wellness in Europe, and beyond.

Objectives

1. Championing harmonised health information and standards for capturing, curating, protecting and exchanging health data in a trustworthy, legally compliant and transparent manner using best practices. This is to enable complete and interoperable health records on individuals and populations to deliver benefits to all stakeholders, supporting and guiding the best use of standards and assets for semantic interoperability and privacy protection.

2. Providing and/or fostering capabilities to enable better quality health data, and the legitimate sharing and uses of health data, including:
   - Semantic interoperability info-structures and assets
   - Exchange and research platforms and tools
   - Informatics standards and resources to support standards adoption
   - De-identified health data repositories
   - Research data source catalogues and metadata

3. Facilitating, deriving and using intelligence from health data (scientific and clinical intelligence, research, knowledge discovery, service improvement and business intelligence) through advancing the uses of:
   - Electronic Health Records and Personal Health Records
   - Citizen sourced data
   - Mobile health sources
   - Social care records
• Disease, device and quality registries
• Reimbursement claims and reporting databases
• Cohort studies and Bio Banks
• Clinical trial and electronic case report forms (eCRF)
• Other potential sources of health related data

4. Performing and commissioning quality assessments, and conducting or overseeing quality audits of:

• Health related ICT systems and applications
• Health data
• Personnel using health data
• Relevant organisational processes

5. Building synergy and consensus: acting as a focal point bringing stakeholders together to share experiences, agree common priorities and approaches for maximizing the benefits of good quality and interoperable health data and the trustworthy reuse of health data, working towards convergence and cross-fertilization between:

• Patient associations
• Citizen, family and carer associations
• Health professional associations
• Clinical and informatics academia
• Healthcare providers
• National decision makers
• Third party payers, commissioners
• EHR system and applications vendors
• Medical Device vendors
• Pharma, Bio-tech
• Health data aggregators and consumers
• Regulators
• Standards development organisations (SDO)
• Multi-national decision makers
• Social care providers
• Electronic health (eHealth) competence centres
6. Defining and supporting the adoption of best practices in information governance, including ethics, privacy protection, and codes of conduct, relating to the trustworthy use of health data including capture, processing and sharing.

7. Defining and driving a cohesive strategy and vision for ICT (eHealth, pHealth, mHealth) supported, person-centred care, wellness and prevention, especially from data and knowledge perspectives.

8. Creating awareness and promoting the Institute and its objectives, promoting the value of high quality health data, and delivering training and education in topics relating to its objectives.

9. Ensuring sustainability of the Institute and of initiatives within the health data ecosystem, through business model innovation and value assessment (including health benefits, cost-effectiveness, financial impact, etc.), by developing assessment frameworks and tools, and by collating and disseminating the existing and future evidence of value from catalysing the development and implementation of well-coordinated interoperable eHealth strategies and programmes.
The Business model

Two factors are fundamental to TRANSFoRm's participation in I~HD and other academic and commercial projects.
1. Detailed specification of all the software tools and models developed by the project.
2. Software archiving via source forge or equivalent
3. Documentation and user guides
4. Maintenance of validation materials
5. Versioning of new versions.
6. Protection of intellectual property.

The proposed business model is that TRANSFoRm focuses on 3 main drivers. Firstly maintaining the data eco-system, secondly providing advisory services and linking to other research projects that will integrate its deliverables / components into commercial applications and finally custom software development based on the TRANSFoRm deliverables. These drivers will be met through I~HD unless an individual TRANSFoRm participant is able to deliver its components.

The result of which is that TRANSFoRm:
1. Continues to operate as a consortium rather than a legal entity, but will work closely with I~HD.
2. Partnership members are consortium members who chose to continue working on TRANSFoRm exploitation activities and wish to develop the TRANSFoRm tools further
3. TRANSFoRm software is licensed under an open-source agreement for free
4. Consortium members provide value-add services, i.e. consulting and custom software development which generate revenue for members should they wish, or via I~HD

The consideration of providing certification services is considered difficult as TRANSFoRm currently does not fulfill typical requirements needed to operate as a certification provider, however EuRoRec has this capability and may be performing this task for I~HD.
Business model advantages

The proposed business model reflects the realities of customer needs and consortium members’ capabilities.

There are three advantages of this business model:

1. A lean organisational model that requires limited infrastructure and effort to sustain, and virtually no management overhead
2. Promotion of a rich and vibrant eco-system of developers, applications, and support available for customer's needs while collaborating with other similar projects, such as EHR4CR via the I~HD.
3. Delivery and distribution of TRANSFoRm components and value-add services left to the network of TRANSFoRm consortium members either individually, as a consortium or via I~HD.

Business model disadvantages

- Business development and delivery opportunities compete with other efforts that TRANSFoRm consortium members are engaged in
- Merging several projects, such as TRANSFoRm, EHR4CR and EuroRec requires alignment of components and services alongside roles and responsibilities in order to create an effective go-to-market approach and to provide a clear picture to any external parties, such as EHR vendors, of what the scope and remit of such a merged entity is. The I~HD has been through an extensive development and we believe these issues have been addressed. Please refer to the I~HD website for details on services, partner engagement and institute governance/membership.
- Agreement in principle has been reached with I~HD, but detailed discussion as to Intellectual Property protection and contribution to project steering are yet to take place.

TRANSFoRm will continue to operate as a network of project participants, but attempts to maintain and develop software platforms after a project, whilst also promoting their use carry a significant overhead. These tasks will be devolved to I~HD, without prejudice to the TRANSFoRm consortium agreement where individual participants are allowed to exploit project IP. Table 3 shows the breakdown of tasks between I~HD and TRANSFoRm.
Table 2. Responsibilities of TRANSFoRm stakeholders and I-HD

<table>
<thead>
<tr>
<th>Responsibilities</th>
<th>I–HD</th>
<th>TRANSFoRm Consortium Members</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Maintains relationship with EU-wide activities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Maintains partnership structure and defines governance model with other partnership members</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Promotes the TRANSFoRm platform</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Serves as single point of contact for external requests</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Negotiates with external customers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Co-ordinates project delivery with external customers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Communicates with partnership members</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Current consortium members take responsibility for their respective TRANSFoRm component(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Promote their respective TRANSFoRm component and provide information for business purposes</td>
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<tr>
<td></td>
<td></td>
<td>• Support contract negotiations</td>
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<tr>
<td></td>
<td></td>
<td>• Deliver their components to relevant projects and provide consulting and custom development services</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Maintain and improve their components over time via additional LHS-related projects, funded at national, EU and international levels.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Communicate with management and other partnership members</td>
</tr>
</tbody>
</table>
Operational Framework – Business Development

Figure 2. below outlines the business development framework for TRANSFoRm. The framework highlights the single point of contact between the customer and TRANSFoRm management (to be represented by I-HD) whilst representing the interests of a wide range of consortium members.

TRANSFoRm also integrates with EU-wide initiatives to provide maximum synergies to its external collaborations.

Figure 2. Business development framework for TRANSFoRm
Operational Framework – Delivery

Figure 3 highlights the four stage delivery framework for TRANSFoRm. Similar to the sales framework a single point of contact is utilized with the TRANSFoRm management representing the interests of consortium members.

Figure 3. Delivery framework for TRANSFoRm
TRANSFoRm Exploitation Plan

Based upon the critical success factors identified by user groups, SWOT analysis, review of the business model and operating framework there are three key strategies that should form the core of future TRANSFoRm development.

The first strategy is to continue to strengthen the value proposition of TRANSFoRm to EHR system providers (Table 3). The second is to prioritise engagement of EHR system providers based upon segmentation by country (Error! Reference source not found.). Finally TRANSFoRm must continue to disseminate success stories supported by the results of the demonstration 1\(^2\) and 2\(^3\) use-cases, and evaluations of all three use cases to drive demand for usage (Table 4 Results from demonstration 1 and 2 reports that should be disseminated to drive demand for usage).

Table 3. Further strengthening the value proposition of TRANSFoRm to EHR system providers

<table>
<thead>
<tr>
<th>Current ‘as is’ status</th>
<th>Aspirational status</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Saving on development cost by adopting TRANSFoRm open source software components</td>
<td>• Agile development of collaborative platform solutions</td>
</tr>
<tr>
<td>• Enhancing the adoption of EHR systems by providing an easier, more accurate, and faster means of entering data allowing to reach more customers</td>
<td>• Become a frontrunner of EHR market growth and evolution via I~HD</td>
</tr>
<tr>
<td></td>
<td>• Enter an adjacent market whereby data aggregation has the potential to be monetised</td>
</tr>
</tbody>
</table>

Table 4 Results from demonstration 1 and 2 reports that should be disseminated to drive demand for usage

<table>
<thead>
<tr>
<th>Goals</th>
<th>Demonstration 1. Finding eligible cases for RCT recruitment</th>
<th>Demonstration 2. Passing eSource data to a commercial eDC provider</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To demonstrate that TRANSFoRm’s technical tools can provide value-added benefit to pharmaceutical companies</td>
<td>To showcase that the TRANSFoRm infrastructure is able to communicate with a commercially available electronic data capture system (eDC)</td>
</tr>
</tbody>
</table>
**Demonstration 1. Finding eligible cases for RCT recruitment**

Data from electronic health records databases (i.e. NIVEL and CPRD) has the potential to help identify patients for trial recruitment more effectively and efficiently compared to common practice today, which is more reactive rather than proactive.

The extraction of data from NIVEL Primary Care database via the TRANSFoRm QWB confirmed functionality of the DNC between TRANSFoRm and NIVEL as well as providing a usability assessment of the QWB itself.

**Conclusion**

The successful transfer of study participant data from a live study into the Merge eDC platform successfully demonstrates the interoperability of a commercially available system with the TRANSFoRm study system. Interoperability is defined narrowly as the ability to pass a data element accurately, with its associated metadata to the eDC.

The proof-of-concept migrated data from thirteen study participants with each study participant providing two pages, an Informed consent and CROM page. The accuracy of the data transfer was validated by a data consistency questionnaire. This is the first step in showing the potential of the TRANSFoRm study system in a commercial environment.

**Reference**

[2] [3]

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**Table 5. Summary of TRANSFoRm project outputs and their associated exploitation plans**

<table>
<thead>
<tr>
<th>TRANSFoRm output</th>
<th>Exploitation plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Privacy model: A ‘zone’ model with an explicit method of graphically depicting the zones and operation of filters between zones</td>
<td>Published method (17)</td>
</tr>
<tr>
<td>TRANSFoRm output</td>
<td>Exploitation plan</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>2. Provenance infrastructure: Based on the Open Provenance Model [REF] each infrastructure component captures a provenance trace that enables reconstruction of an audit trail for any given data element.</td>
<td>Published method (18)</td>
</tr>
<tr>
<td>3. Clinical Prediction rule ontology based web service</td>
<td>The Diagnostic Ontology has been made available as a public download in OWL format on the TRANSFoRm website (<a href="http://www.transformproject.eu">www.transformproject.eu</a>). A future project is required to extend the data beyond the three initial reasons for encounter.</td>
</tr>
<tr>
<td>4. Research data model</td>
<td>CDIM(12) and CRIM(13) have been published. A full description of the use of CDIM and CRIM in the construction of data node connectors will be published and made available on the TRANSFoRm website.</td>
</tr>
<tr>
<td>TRANSFoRm output</td>
<td>Exploitation plan</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>5. eCRF</td>
<td>Extension of CDISC ODM and SDM by the incorporation of archetypes with references to the CRIM and CDIM models will be published and discussions are ongoing with CDISC regarding future incorporation into the standards. A reference implementation of the clinical trial system will be maintained within the European Institute. At present individual archetypes have to be written by hand, discussions are in hand for the production of an archetype authoring tool.</td>
</tr>
<tr>
<td>6. Data Federation</td>
<td>A reference implementation of the genotype-phenotype study system will be maintained within the European Institute. Search authoring tools will be available open-source.</td>
</tr>
<tr>
<td>7. DSS integration</td>
<td>The DSS is currently integrated with the INPS Vision3 system. Further work is required to move this to a data-node connector/CDIM based flexible system</td>
</tr>
</tbody>
</table>
Summary
The thinking around the strategies that drive the exploitation plan takes its heritage from the core concepts of the original exploitation strategy1 and refines them based upon them with the identified critical success factors, SWOT analysis, business model and operating framework.

The key strategies for an ongoing exploitation plan are:

• To continue to strengthen the value proposition of TRANSFoRm to EHR system providers
• To prioritise engagement of EHR system providers based upon a segmentation by country
• Continue to disseminate success stories supported by the results of the demonstration 12 and 23 use-cases to drive demand for usage

The SWOT analysis reveals the strengths of TRANSFoRm to be the platforms demonstrated compatibility with commercially available software as demonstrated by the use cases. A key opportunity for TRANSFoRm is to use the strategies described above to seek mergers with similar projects in order to provide a broader portfolio of available components that could be leveraged. The chief threat facing the TRANSFoRm exploitation plan is overlapping with similar projects or commercial vendors leading to market competition or confusion over the value proposition. Both these are solved by participation in I–HD.