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GRIMALDI STUDIO LEGALE

EASME/COSME/2018/004
Big Data and B2B platforms: the next big opportunity for Europe

BROCHURE

Final conference on the final results of the study

November 26, 2020

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Introduction

The European Commission and the Executive Agency for Small and Medium-sized Enterprises (EASME) are conducting the study **"Big Data and B2B platforms: the next big opportunity for Europe"** with the objective to analyse how to accelerate the growth of the data-based economy and to support the development of B2B platforms in Europe focusing on two sectors: **automotive** and **healthcare**.

This study gives particular attention to the opportunities offered by Big Data and B2B platforms for **Small and Medium Size Enterprises (SMEs)**, with the purpose of maximising their innovation potential and contributing to growth and employment in Europe.

Wavestone is leading this study, in partnership with the ICCS-NTUA (National Technical University of Athens), TNO (Netherlands Organisation for Applied Scientific Research), KOMIS and CEPS. GRIMALDI Studio Legale provides legal advice transversally to all work packages.

The study started on the 20th December 2018 and will end on the 19th December 2020, for a total duration of two years. Under this study two pilots have been developed, one for each sector being analysed.

On the one hand there is the sector of **automotive** that is covered by **Work Package 1** (WP1), namely "provide the business case for **'fair and equal' data sharing for cooperative, connected and automated mobility**". This work package is centred around the design and implementation of a pilot to prove the concept of a possible **solution** that can help **improving fair and undistorted competition,** notably **equal access for all market participants to in-vehicle data,** through the use of **shared data platforms**.

And on the other hand, there is the sector of **healthcare** that is covered by **Work Package 2** (WP2), namely "explore the feasibility of a pilot that promotes and stimulates **strategic investments in high-impact healthcare related projects**". This work package aims to design and implement a pilot to build a **pan-European, high-quality, diabetes-related data repository** by using the latest technologies and big data breakthroughs. The pilot will be used to study the challenges and opportunities of a **type 2 diabetes (T2D) health data marketplace**.

Eight stakeholder workshops were held as part of the study, four for each sector analysed. The results of the workshops were disseminated through workshop reports[1] and were used to inform the four phases of the pilots, i.e. Inception, Design, Implementation and Finalisation of the outcomes phases.

Due to the extraordinary circumstances of the COVID-19 pandemic, the **Final Conference** will be adapted into an online event with the ZOOM conferencing platform. The conference will be an

[1] The study material, including the various workshop reports, is available at: https://ec.europa.eu/growth/industry/policy/advanced-technologies/industrial-applications-artificial-intelligence-and-big-data/big-data-b2b-digital-platforms_en

opportunity to present the **final results of the study** and discuss the **main lessons learned** with policymakers and stakeholders.

The morning session of the conference will be dedicated to presenting the European perspective on the opportunities of Big Data and B2B platforms in Europe that will be confronted with different approaches and perspectives outside of the European Union. In addition, key findings and results from data platforms in the automotive and healthcare sectors will be presented.

In the afternoon, a panel will take place with high-level experts who will provide an overall assessment of the study and finally present ideas and recommendations for future action and research.

This brochure provides an overview of the study and the objectives of the two pilots that have been developed. The organisation of the work carried out as part of the study is also presented, as well as an overview of the main activities and deliverables achieved over the two years of the study. Finally, the objectives of the final conference and a brief explanation about its organisation are provided.

1 About the study

The European Commission and the Executive Agency for Small and Medium-sized Enterprises (EASME) is conducting the study "**Big Data and B2B platforms: the next big opportunity for Europe**" with the objective to analyse how to accelerate the growth of the data-based economy and to support the development of B2B platforms in Europe focusing on two sectors: automotive and healthcare. The specific objectives of this study can be summarised as shown on the right.

Objective 1

Enable businesses, especially SMEs, to take advantage of the opportunities offered by large data

Objective 2

Design and implement two large scale pilot projects: one for connected and automated systems and the other to build a high-quality pan-European diabetes data repository, using the latest technologies and major advances in data science.

Objective 3

Promote and stimulate strategic investment in high-impact projects in the above-mentioned areas.

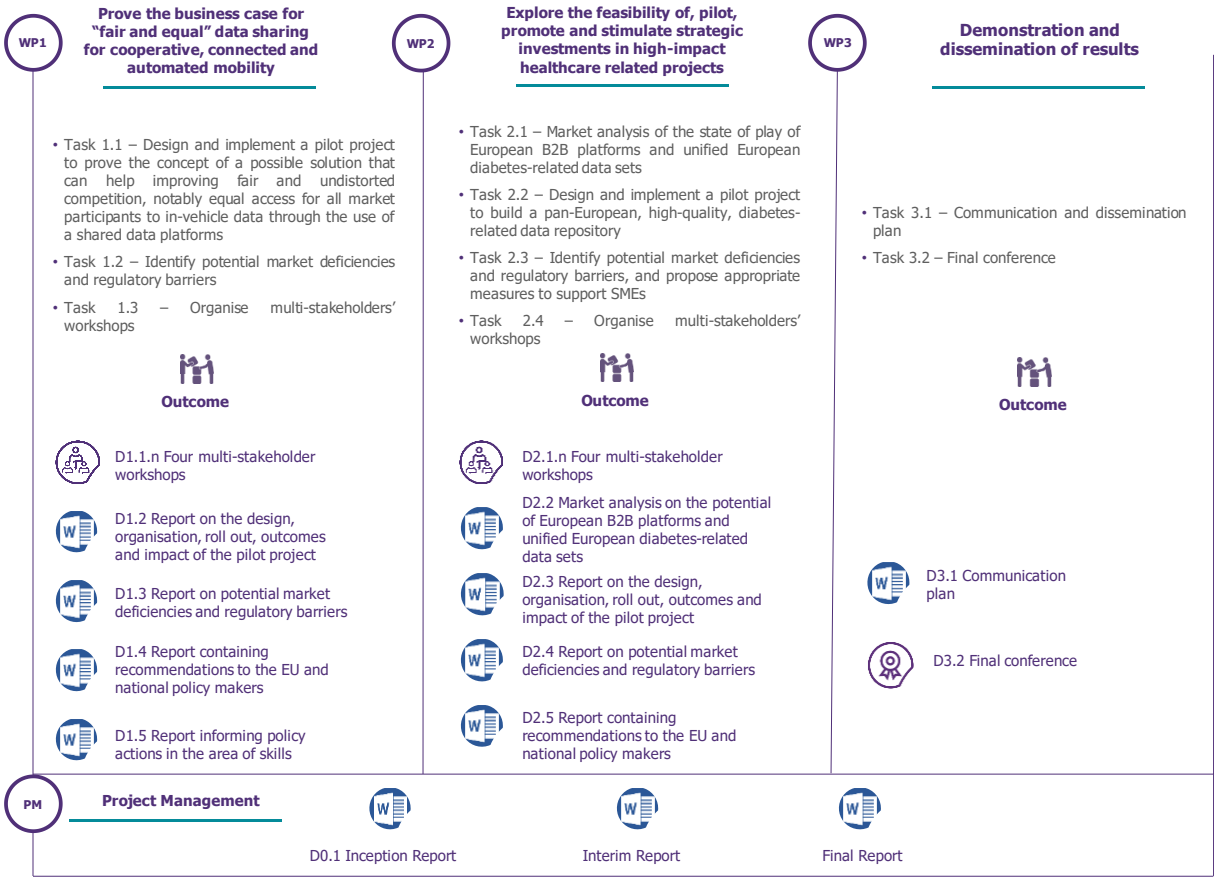
Objective 4

Support the participation of SMEs in the data economy by identifying barriers and recommending possible solutions.

The study started on the 20th of December 2018 and will end on the 19th of December 2020, for a total duration of two years.

The study is structured **around three Work Packages (WPs)**; two WPs dedicated to the pilots for each of the two sectors (**automotive and healthcare**), and the third cross-cutting WP supporting the study through demonstration and dissemination activities. Below an overview of the work packages, associated activities and deliverables is provided.

Figure 1 Overall framework



Source: Authors' elaboration.

2 Objectives and scope of the two Pilots

2.1 Pilot dedicated to the automotive sector - WP1

The objectives of the pilot dedicated to the **automotive sector**, namely "prove the business care for '**fair and equal' data sharing for cooperative, connected and automated mobility"** can be summarised as follows:

- To **prove the concept** of a possible solution that can improve fair and undistorted competition, notably equal access for all market participants to in-vehicle data using a shared data platform.
- To **provide input** for studying and demonstrating the **potential impact of a shared data platform on the European market**, specifically by analysing the opportunities and benefits it offers for independent third-party service providers, notably SMEs, as well as the potential risks of market distortion by the frontrunners (i.e. the winner takes all effect).
- To **provide insights** into a **set of required capabilities** and **economic and technical competences** of third-party service providers and repairers to help further modernise and develop the European market for connected and automated vehicles. To this end, during the

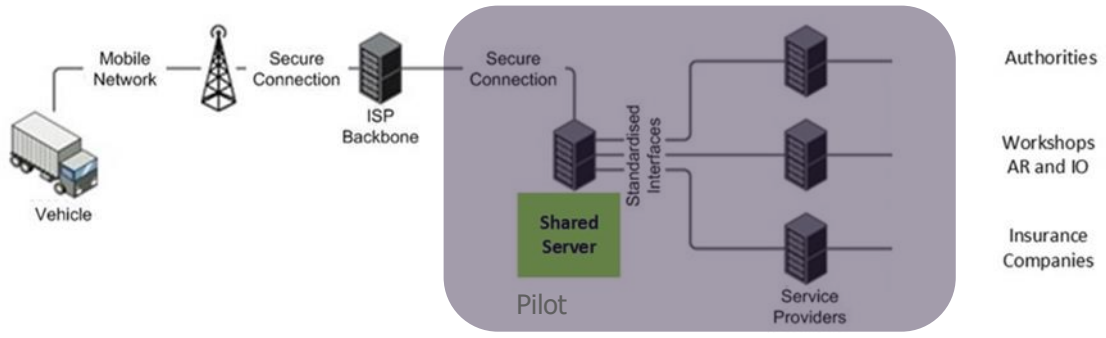
pilot, the study team focused on competences and other issues such as data privacy, cyber security, liability risks, legislative frameworks for operation, data ownership and IP rights protection.

- To **deliver an architecture** that will **help industry stakeholders** and **policymakers** to formalise a common position based on a set of principles for the creation of shared EU-wide in-vehicle data platforms, available on equal terms to all interested service providers in order to fuel an open data-driven market of innovative products and services.
- To **provide technical input for drafting sector-specific recommendations** to EU and national policymakers, as well as to industry; and for developing an action plan for all stakeholders to overcome existing barriers and ensure a level playing field and fair competition in this market.

The pilot implements **scenarios that are based on the "Shared Server solution"**[2].

The "**Shared Server solution**" is a technical architecture proposed by the study "Access to In-vehicle Data and Resources"[3]. It is based on the concept of a **"data server platform**" where relevant vehicle data are transferred to an external server and made available to service providers. The concept entails a connected vehicle that communicates to shared servers via mobile networks. Subsequently, data from all vehicle manufacturers will be sent to a shared data server from where service providers can access data via a standardised interface, as shown in Figure 2.

Figure 2. Shared Server solution



Source: "Access to in vehicle data and resources" study.

The "Shared Server solution" must be **operated by an independent provider**, which is commissioned by a consortium of interested stakeholders ideally including Original Equipment Manufacturers (OEMs). Data available at the standardised interfaces should be of the same quality as the data of OEM backend. **Shared Server will give equal access to in-vehicle data** and will make the party accessing the **data anonymous** from the point of view of the manufacturers thereby allowing fair competition.

[2] https://ec.europa.eu/transport/sites/transport/files/2017-05-access-to-in-vehicle-data-and-resources.pdf
[3] https://ec.europa.eu/transport/sites/transport/files/2017-05-access-to-in-vehicle-data-and-resources.pdf

From a technical point of view, **in-vehicle data are 'Big Data'** in terms of volume and velocity. In our scenario, huge data sets from individual vehicles will be streamed down to a platform for sharing among SMEs and third parties in a fair and equal way.

The scope of the pilot covers **the following framework:**

- The Shared Server operator tasks as well as the role of potential service providers that exploit the data which are provided by the Shared Server;
- The user's consent management, the data streaming capabilities, the exploitation of data on rest or aggregated data by services providers; and
- On the service provider side, potential service groups are examined for their feasibility and effectiveness, taking into account technical and liability issues.

During the development of the pilot, issues regarding the proper data subset of the in-vehicle data that could be shared with third-party service providers and the possible solution to provide them via common and open interfaces were investigated.

2.2 Pilot dedicated to the healthcare sector - WP2

The objectives of the pilot dedicated to the **healthcare sector**, namely "explore the feasibility of a pilot that **promotes and stimulates strategic investments in high-impact healthcare related projects**" can be summarised as follows:

- To **extract and exploit data sets** from both, **'omics' profiling and other biomarkers** from key European and national research projects or prospective **cohorts related to T2D**. These data could be used to develop a comprehensive biomarker package that quantifies the relevant processes of the metabolic flexibility system and determines an individual's metabolic health trajectory and predisposition to certain conditions.
- To **combine such data repository** with **Real World Evidence (RWE)** data. RWE is defined as healthcare information that is derived from multiple sources outside the typical clinical research setting.

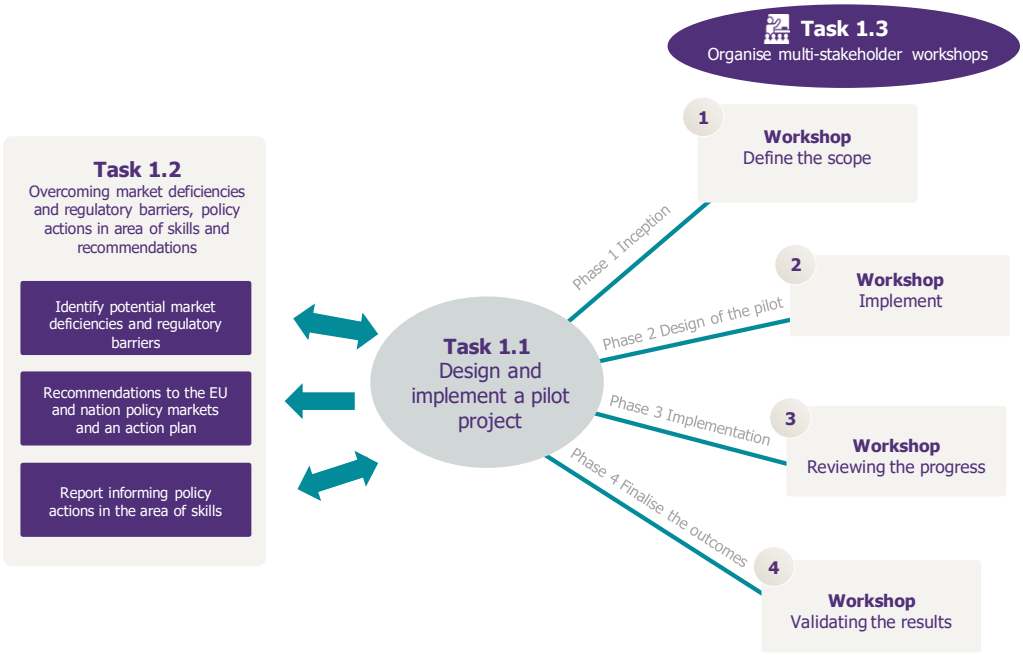
The **ultimate objective of the pilot** is to design and implement a pan-European, high-quality, diabetes-related data repository by using the latest technologies and big data breakthroughs (prototype). The final IT infrastructure should provide a catalogue where the various stakeholders are able to find a fair description of the health data available without having to directly connect to the owners of the data, which can be both research institutes (anonymised research data) as well as patients. The development, design and implementation of the pilot took into consideration **several risks** that were identified at the beginning of the study. The most important risk that was identified is data quality. Use within clinical applications, especially, need high quality data. Standardisation of research data can at least help to identify the level of quality of the data. Provenance of data is therefore key. Another risk is the lack of context of data. This is especially the case for self-reporting, or data gathered by individuals through wearables.

3 Organisation of the work

3.1 Organisation of the work package dedicated to the automotive sector – WP1

Firstly, the pilot was developed by, designing and implementing a pilot project to prove the concept of a possible solution that can help improve fair and undistorted competition, notably providing equal access for all market participants to in-vehicle data through the use of a shared data platform. This task corresponds to (**Task 1.1, WP1**). Secondly, potential market deficiencies and regulatory barriers were identified, to get to trial appropriate measures to support SMEs to participate in that market under fair conditions. As part of this task, sector-specific recommendations to the EU and national policymakers and industry were also developed. Finally, as a specific area of policy attention, a set of relevant policy actions in the area of skills were mapped so to link the work done under the automotive work package with other ongoing initiatives and support the creation of a comprehensive framework for digital skills at European level (**Task 1.2, WP1**). Four workshops were carried out throughout the study, one for each phase of the pilot, to discuss the progress and validate, with selected experts, the intermediate and final results of the work done under the automotive work package (**Task 1.3, WP1**). Figure 3 is an overview of the structure of the work of Work Package 1 which covers the automotive pilot.

Figure 3 Task organisation of WP1 – automotive pilot

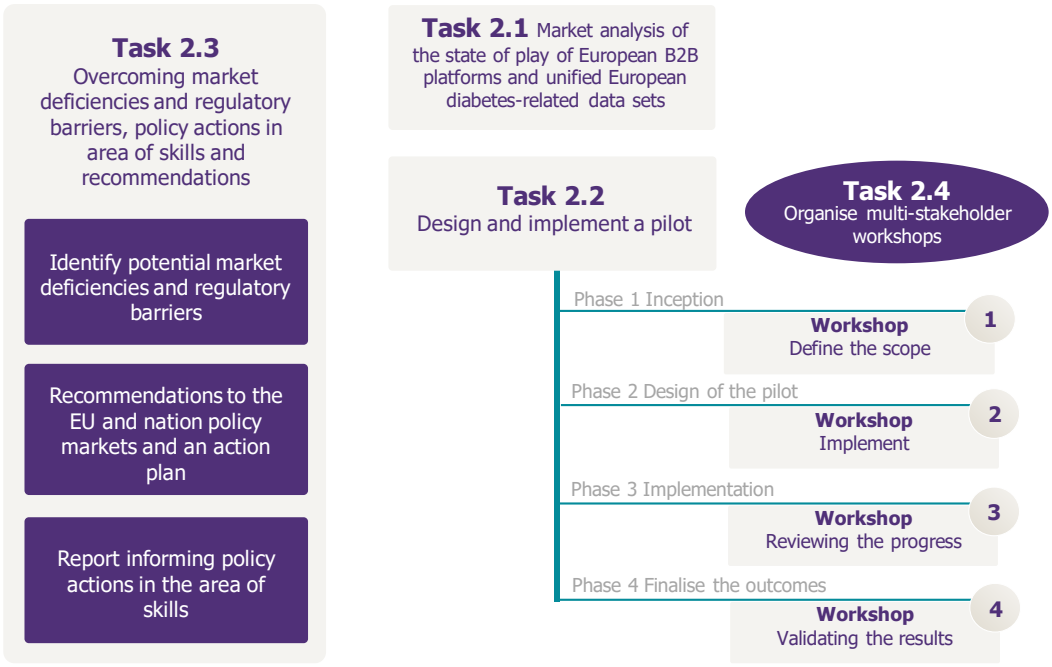


Source: Authors' elaboration.

3.2 Organisation of the work package dedicated to the healthcare sector – WP2

Firstly, a market analysis of the state of play of European B2B platforms and unified European diabetes-related data sets and FAIRification of data was carried out (**Task 2.1 of WP2**). Secondly, the pilot was designed, implemented and extended. The focus was on two use cases that represent good examples and clear views of the problem. The use cases aim to demonstrate the weaknesses and barriers as well as the business opportunities of data sharing and new scientific findings (**Task 2.2 of WP2**). Thirdly, a study focusing on overcoming market deficiencies and regulatory barriers was conducted (**Task 2.3 of WP2**). The design and implementation of the pilot were supported by a series of multi-stakeholder workshops (**Task 2.4 of WP2**). Four workshops were carried out under the work package dedicated to healthcare, one for each phase of the pilot, to discuss the progress and validate, with selected experts, the intermediate and final results of the work done. Figure 4 is an overview of the structure of the work of Work Package 2 which covers the healthcare pilot.

Figure 4 Task organisation of WP2 – healthcare pilot



Source: Authors' elaboration.

4 Overview of the main activities and deliverables over the two years of the study

4.1 Pilot on "fair and equal" data sharing for cooperative, connected and automated mobility - WP1

Inception phase

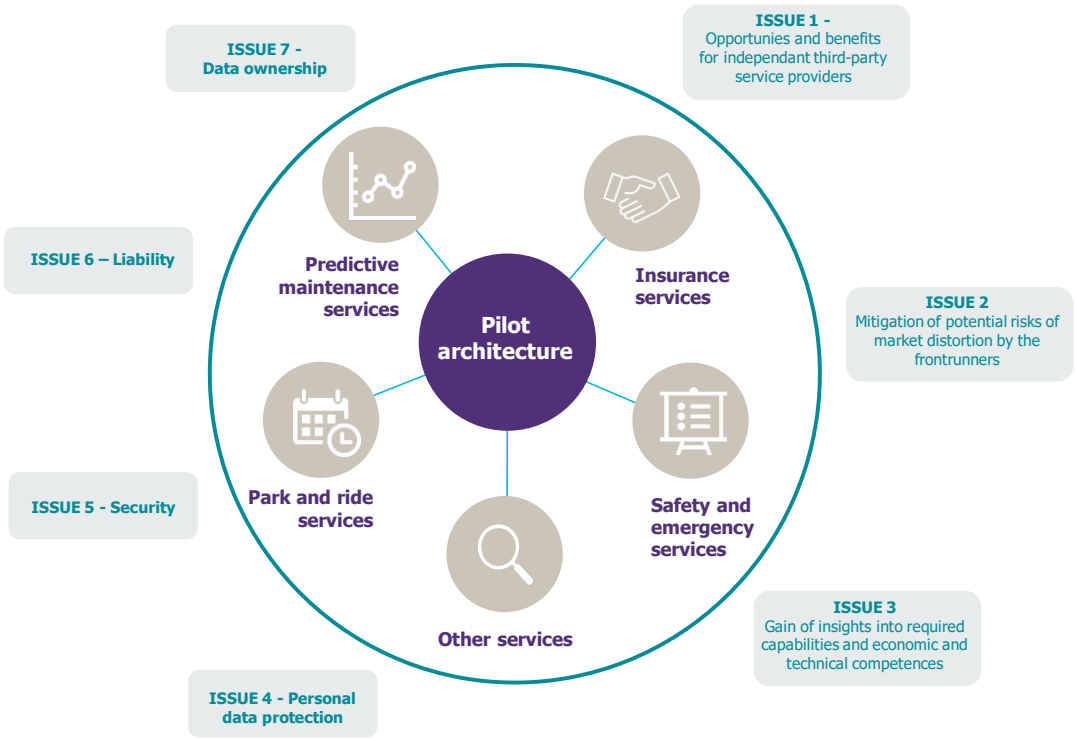
Based on the understanding of the Shared Server Solution architecture for the provision and exchange of big data, a number of issues were identified during the **Inception phase** of the pilot up to the execution of the **first workshop**. These issues included i) opportunities and benefits offered by the Shared Server architecture for independent third-party service providers, ii) mitigation of potential risks of market distortion by the frontrunners (i.e. the winner takes all effect), iii) insights of the economic and technical competences and skills required of third-party service providers and vehicle repairers, iv) personal data protection, anonymisation, user consent and security, vi) liability, and data ownership and a way to address each of these issues during the pilot implementation was proposed.

These issues served as a basis for discussing **specific Shared Server requirements** extracted from the literature[4,5,6] and discussed during the first workshop (more information can be found in the First workshop report at the section 'Views on the Shared Server architecture, tamper-proof access and data reliability'). Based on discussions during the workshop, the requirements were finally grouped into the following groups: i) operator, ii) architecture, iii) user, iv) restriction, v) competition, vi) development and approval of services, and vi) attribution of liability and further analysed in view to execute the next pilot phases.

Additionally, a number of **services** to be potentially provided under the Shared Server architecture was proposed and grouped according to different categories based on the domain they are applied within, the data needed and latency required for their implementation and rollout, namely: i) safety and emergency ii) insurance services iii) maintenance iv) parking and v) other services. Figure 5 below depicts the services to be provided including a link with the issues identified.

[4] Policy Position on car connectivity by FIA, 2016
[5] C - ITS / WG6, ANNEX 4: FIA – interim solution Data Server Platform; Shared Server 2015-09-03
[6] C - ITS / WG6, ANNEX 17: FIA Answers on ACEA responses and further explanation of the "Shared Server Concept", FIA explanation of the Shared Server Concept V1.0.docx, 2015-11-20

Figure 5. Services to be provided including a link with the issues identified



Source: Authors' elaboration.

A **prioritisation of these services** according to the perceived importance and potential for improvement under a Shared Server architecture was carried out during the first workshop (more information can be found at the section 'Proposed set of services' of the First workshop report).

Open **issues on liability** (contractual and extra-contractual), **data ownership** and the current EU legal framework as well as **competition barriers** were also analysed during the Inception phase of the pilot and discussed during the first workshop (more information can be found at the section 'Liability, ownership and competition barriers' of the First workshop report).

Design phase

During the **Design phase**, the pilot development was focused on identifying and addressing the main issues arising from the pilot implementation of the Shared Server architecture, touching upon the issues of data transmission, semantic interoperability and standardisation. Furthermore, the services identified during the first workshop were coupled with pilot data and reviewed in view to reach feasibility and efficiency. The issues of data privacy were further explored through the investigation of user registration flows and methods for services and service providers registration. More specifically, the Design phase of the pilot covers the Shared Server operator tasks as well as the role of the potential service providers that exploit the data which are provided by the Shared Server.

In addition, the architectural elements of the implementation as well as the Azure platform's components that could deliver a robust solution were recognised during the Design phase. A realistic data set has been elaborated for further experiments, giving outcomes on the computational efficiency and latency

barriers. Based on suggestions from FIA and ACEA collected through the **second workshop**, a subset of the in-vehicle data that could be shared with third-party service providers was proposed. Then, a solution on the user's and the provider's registration flow focusing on user consent management needs in relation to data streams and data on rest was developed. Finally, on the service providers side, flows of potential groups of services were developed taking into account technical and liability issues. The study team also designed a feasible solution for providing them via a common and open interface.

The selected services and use cases that were implemented were presented during the second workshop as well as the experimented realistic data. The workshop participants could test the pilot platform and discover the big data capabilities of the architecture. Finally, a demonstration of the Azure platform was given to the workshop participants and feedback was collected (more information about the outcomes of the second workshop can be found in the Second workshop report).

Implementation and Rollout phase

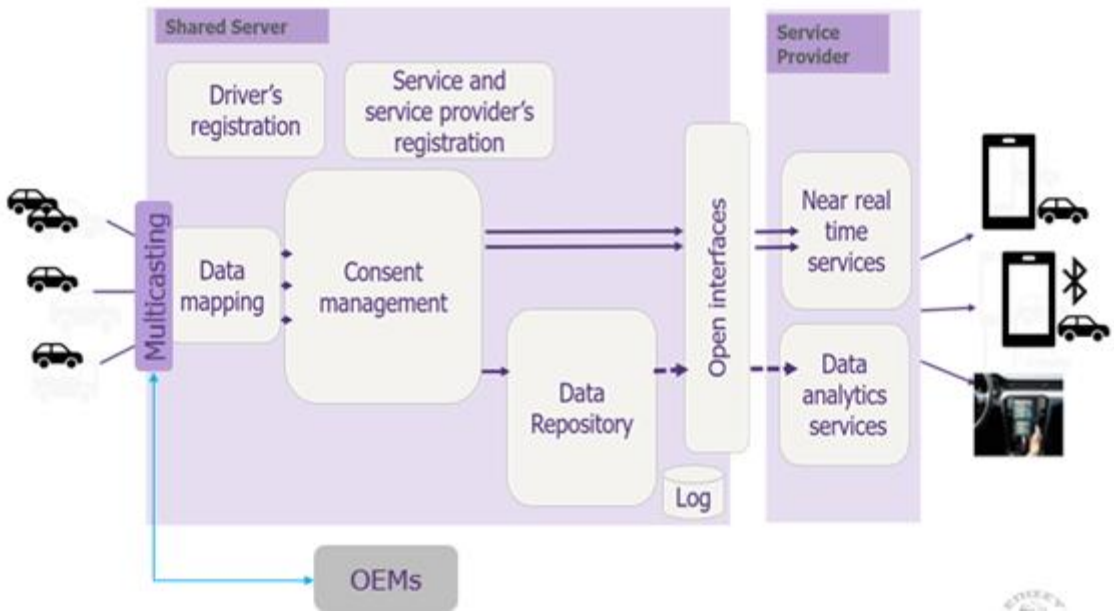
During the **Implementation and Rollout phase**, the study team followed an iterative agile methodology. As part of this methodology, the following activities were conducted and finalised at the end of the phase following the third workshop:

- **Elaboration of the requirements**: the study team focused on the requirements and finalised the detailed design.
- **Coding and testing**: the study team delivered applications, app. interfaces, queries, resulted datasets, as well as data evidenced analysis, observations, estimations, etc.
- **Evaluation of the results**: the study team examined the results in terms of consistency and completeness and evaluated them against the objectives and targets of the development that were set up by the Design phase.
- **Refinement of the objectives and goals:** having in mind the big picture from a wide range of sources identified though desk research, surveys and interviews of the workshop participants as part of the agile methodology, the study team refined the objectives of the pilot development and setting higher goals. Therefore, several hypotheses were tested in order to provide a secure communication channel between the vehicle and the OEMs within the Shared Server architecture. Furthermore, several additional use cases and services that would be tentatively demonstrated in the future pilot development were investigated.

Regarding the coding and testing activities, the Consent Management module for the "Shared Server" role was successfully developed, and the APIs based on widely accepted standards were also deployed for the "Service Provider" role. This resulted in the following two data products for the Shared Server platform:

- Streaming data via Advanced Message Queuing Protocol (AMQP) messages.
- REST based web services providing data at rest upon request of the "Service Provider".

Figure 6 The Big Picture, the main roles in Shared Server pilot



Source: Authors' elaboration.

On top of this, the "Hazard Location Notification Service", the "Park and Ride" service, the "Usage Based Insurance", and "Usage Based Monitoring and Scoring (Eco Score)" as part of the "Service Provider" role of the Shared Server concept, were developed.

In the **third workshop** that concluded the Implementation and Rollout of the pilot phase, the progress of the implementation process on the big data platform was presented to the participants. A session focusing on the challenges of connected and automated vehicles aiming to drive refinements and improvements of the pilot was given to the participants and feedback were collected. Finally, the synergies with the Blueprint on skills initiatives and the report informing policy actions in the area of skills regarding service development on connected vehicles were presented (more information about the outcomes of the third workshop can be found in the Third workshop report).

Finalisation of the outcomes phase

During the **Finalisation of the outcomes phase** of the pilot, the study team consolidated the insights gathered during the third workshop to arrive to the final setting of the pilot and its features. The experiments, new data sets and applications contributed by the participants during the third workshop were considered and reviewed. In addition, the following two important issues were developed:

- Mitigating the potential risks for market distortion by the front runners; and
- Awareness of the economic and technical capabilities and skills required of third-party service providers.

The **fourth workshop** closed the implementation and rollout phase of the pilot and its main objective was to present and validate the final results of the pilot to the participants. This last workshop was the opportunity to demonstrate the team's recent developments regarding the introduction of Kafka platform to the Shared Server architecture to deliver secure and low latency back and forth communication between the vehicles and the OEMs and a presentation of our suggestions for anonymising Shared Server's data to foster the secondary use of them. The policy recommendations to support data sharing in the automotive sector, focusing on the urgency of action and the role of stakeholders were also presented during the workshop. And finally, a presentation was given aiming at showing that the implemented pilot meets the need of service providers for developing innovative services in a fair and undistorted market.

The fourth workshop report will be soon available on the study webpage.

4.2 Explore the feasibility of a pilot promoting and stimulating strategic investments in high-impact healthcare related projects - WP2

Inception phase

During the **Inception phase** of the pilot up to the execution of the **first workshop**, the main features of the health data infrastructure were presented, having in mind the overall objective of finding the optimal configuration of the infrastructure for sharing and treating health data exemplified by T2D data (more information about the outcomes of the first workshop can be found in the First workshop report). The state of play in terms of data availability for the development of a T2D data marketplace was another topic analysed during the Inception phase of the pilot, which was closed by the second workshop (more information about the outcomes of the first workshop can be found in the First workshop report).

The objective of the pilot is to allow to test and further develop a **federated infrastructure** that connects data from different research sources (including omics data) and Real-World Data. The pilot addresses two specific use cases that aim to show the added value of such an infrastructure. The study team connected to other diabetes cohorts and incorporated the **FAIR (Findable, Accessible, Interoperable, Reusable)** data principles[7] using a federated infrastructure. For T2D data repositories that can be adapted, the study team:

- facilitated **interoperability** of the system parameters,
- made the API (Application Programming Interface) **findable**;
- added the **accessibility** details to the system to make them FAIR points; and
- made data **reusable.**

[7] https://www.go-fair.org/fair-principles/

The study team built a **prototype of a T2D health data marketplace** that will respect the ownership of data holder, the privacy of citizens/patients and at the same time will allow for valorisation of health data. The most important risks are the data quality and lack of context of data. This is especially the case for self-reporting, or data gathered by individuals through wearables.

Design phase

During the **Design phase** followed by the **second workshop**, the pilot development focused on setting-up structural characteristics for the infrastructure, such as the way to connect different data sources and the application of FAIR principles. In addition, aspects such as ontologies and interoperability issues were considered for their development and two **use cases** were selected. These use cases aim to test the functionality of the infrastructure and show the added value of combining different types of T2D related data. The first use case focuses on **the development of biomarkers for the sub-typing of type 2 diabetes**. This use case applies data from research studies of different sources. The second use case focuses on **the development of a prognostic model for the development of type 2 diabetes** and applies personal health data.

The second workshop covered: 1) the current status of the infrastructure of the data sharing and, 2) an interactive session on the use cases and needed ontologies/vocabularies. The ontologies for data logics (ONS and ONE), diabetes diagnostics, diabetes treatment, (etc.) were shown (more information about the outcomes of the second workshop can be found in the Second workshop report.

Implementation and Rollout phase

The **third workshop** concluded the Design phase of the pilot and opened the **Implementation and Rollout phase**. During this phase, the databases of data were aligned with the model sent to the data in a secure way. The federated subtyping model was implemented, and its usability was tested. The ontology that addresses personal data was developed as well as the prognostic model for Type 2 Diabetes. As part of this phase, the pilot use cases were implemented on the T2D health data platform. As such, the portal and infrastructure of the pilot were adjusted in an agile way, i.e. rounds of developments were focused on specific goals (and use-cases) and thereby the scripts and portal of the pilot were adapted by new insights during those rounds.

This phase focused on issues related to the opportunities and benefits offered by the IT architecture of the T2D health data platform for independent third-party service providers, as well as liability and data ownership. The **third workshop** was the opportunity to present the progress of the implementation of the T2D health data platform and ask for comments on the implementation process. The participants could therefore review the progress and provide their feedback on the Implementation and Rollout phase. Feedback was asked on the functionality of the system, and the user-friendliness of the interface of the portal. The participants ideas on the next development rounds served to improve the architecture of the platform. This was the opportunity to debate the application of the system in the different use cases. Additionally, the third workshop presented the results of the market analysis. Finally, discussion

with the participants offered the opportunity to gather the expert opinions on the importance of the presented policy recommendations (more information can be found in the Third workshop report).

Finalisation of the outcomes phase

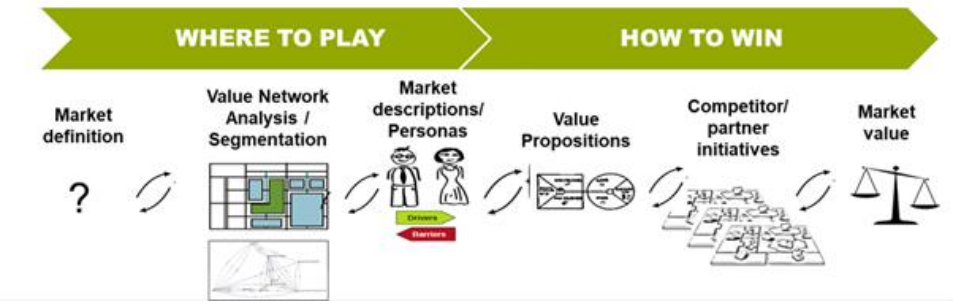
During the **Finalisation of the outcomes phase** of the pilot, the portal was refined on the basis of the feedback received from participants during the third workshop and remains open to all experts participating in this study. The study team continued to improve and expand the portal with databases and tools (e.g. the ontology mapper and the use cases). The **fourth workshop** was an opportunity to present the results of the pilot to be validated with the participants. The status of the infrastructure development and the use cases as well as the outcomes collected during the third workshop were presented and discussed with the audience. Then, several interactive sessions followed to engage the participants into the discussion on lessons learned from the pilot, market issues and legal and ethical issues. The Fourth workshop report will be soon available on the Study webpage.

4.3 Market Analysis on the potential of European B2B platforms and unified European diabetes-related data sets – WP2

As none of the data marketplace initiatives focus on a single health case comparable to the current T2D pilot, a comprehensive **market analysis on the potential of T2D data and databases** was conducted under this study. Therefore, the objective of this market analysis was to assess the market potential for B2B platforms and unified European diabetes related data sets. The market analysis identifies the most important players in the value chain of diabetes-related healthcare and pharmaceutical products and analyses the players active in data collection and use of current data repositories. Furthermore, the market analysis highlights emerging opportunities for innovation, in particular for smaller players, as well as risks of market distortion and opportunity cost of inaction at EU level.

The results of the Market Analysis were presented during the **fourth workshop**. The project team conducted a study[8] following a methodological approach containing the following steps:

Figure 7 Steps of the methodological approach of the Market Analysis study



Source: Authors' elaboration.

[8] Market analysis of the potential of European B2B platforms and unified European diabetes-related data sets (under review)

The overview of initiatives shows that the most relevant initiative for the current pilot is FAIR4Health[9], as this program, comparable to our T2D pilot aims at the standardisation (FAIRification) of health data in relation to the development of business opportunities. Another initiative relevant to the business part of the pilot is Findata, is the Finish initiative that collects (health) data in a centralised health data repository. SITRA[10], which is the Finish innovation fund, plays a central role in developing business models for Findata.

One first important finding stems from the status of T2D patients. The T2D patient group is large and growing, comprising 8.1% of the total population aged 20-79 in the EU28 countries. An average T2D patient will have an education and income below the average for the general population. Only 16% of T2D patients have completed tertiary education, and their average income in 2014 was around EUR 16,833 below the median income for the EU28[11]. They therefore typically have less spending power than the average person, which affects the choices they are able to make for healthy food, healthy behaviors and for their negotiation powers with regard to medical staff and asserting their own rights.

TNO's analysis explored the value networks in this potential market and showed that two separate networks are important:

- the medical network with important players such as (medical) Insurance companies, the Pharmaceutical industry and medical professionals; and
- the healthy lifestyle consumer network with the consumer, food industry and supermarkets.

A very important difference between these two networks is that spending power (and, with that, influence) is high in the medical network and low in the consumer network.

The main stakeholders in these networks are the patient/consumer, the pharmaceutical industry and the health insurance company each with their specific interests and needs.

[9] https://www.fair4health.eu/
[10] https://www.sitra.fi/en/#latest
[11] calculations for EU28 based on Eurostat 2014

Figure 8: Stakeholders in the medical and consumer network

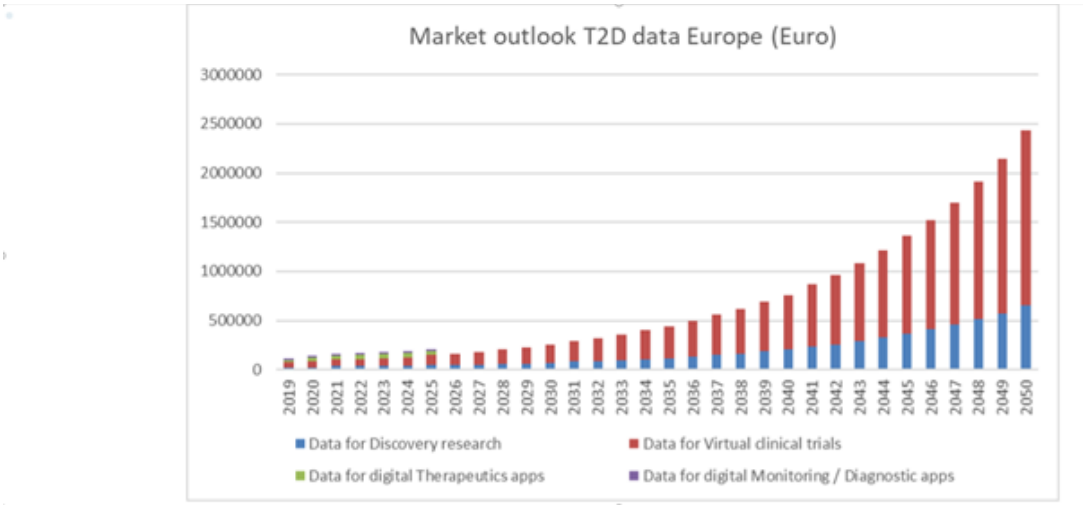
Stakeholder	Interests / needs
Consumer (patient/person at risk)	• Improve health and quality of life. • Evaluate better treatment options. • Understand risks and benefits.
Pharmaceutical industry	• Advanced R&D and pipeline management. • Patent management and strategies. • Determine safety profiles for admission tests. • Assess efficacy and effectiveness.
Health insurance company	• Ensure cost-effectiveness with price arrangements and operational excellence. • Accurate assessment of risks. • Provide evidence-based care. • Good financial investment mix.

Source: Authors' elaboration.

These different stakeholders also have differing data needs. The pharmaceutical industry will be mainly interested in high quality clinical research data and medical claims data, and to a lesser degree patient-powered data. The insurance company will be interested in medical data and medical claims data. For the medical professional/consumer, data for use in diagnostics, health apps and medical records will be important.

The market for health data is not crowded. Only a small number of companies offer health data that includes T2D data. New business initiatives with a good business model and good execution of their critical success factors should be in a good starting position to succeed.

Figure 9: The market outlook for business initiatives from 2019 to 2050



Source: Estimations by TNO, based on Roots Analysis , ASPE, US Department of Health & Human Services , Tufts Center for the Study of Drug Development, and Office of Health Economics

The market for T2D data is therefore a small niche market which for sizable opportunities should be combined with data from other illnesses and other services such as data analytics or data collection services.

Encouraging the use of health apps by consumers to increase the market size is needed, for instance through reimbursement models. Also, there is the need for a common scientific data standard to be able to compare data across databases. And, last but not least, empowerment of the patient/consumer is needed through advocacy organizations concerning issues like data protection, development of health apps and research showing benefits of these apps for the end user.

4.4 Reports on potential market deficiencies and regulatory barriers, including a common industry-led position – WP1 and WP2

Two reports **identifying potential market deficiencies and regulatory barriers in the automotive and healthcare sectors** were prepared within the scope of the study. The report on the automotive sector looks at the entire 'regulatory stack' for the automated vehicles sector as well as at horizontal areas that affect more generally the development of data analytics and data-driven services. On the other hand, the report on the healthcare sector looks at the entire 'regulatory stack' for the diabetes data for the health care sector as well as at horizontal areas that affect more generally the development of data analytics and data-driven services.

At the same time, the reports consider how emerging technological solutions could mitigate existing barriers in the short- to medium term. The work for this report consists of three phases: 1) desk research, 2) fieldwork, and 3) reporting.

Based on the information collected and the stakeholder feedback received so far, the reports analyse obstacles in the following key areas:

- Regulatory barriers, including data protection, data anonymisation, data ownership rights, liability rules and safety issues;
- The role of accountability and trust in fostering data sharing;
- Strategic barriers;
- Interoperability and standards;
- Knowledge and skills.

The two reports potential market deficiencies and regulatory barriers in the fields of automotive and healthcare will be available soon on the Study webpage.

4.5 Report containing recommendations to the EU and national policy makers and an action plan to accelerate the creation of unified EU-wide diabetes related data platform – WP1 and WP2

Based on the identified market deficiencies and regulatory barriers, **two reports** were prepared containing **policy recommendations as well as an action plan** to implement the identified recommendations at both EU and national level with the goal of creating:

- a **shared, EU-wide in-vehicle data platforms** in the automotive sector; and
- a **common diabetes data repository at EU level** in the healthcare sector.

For each of the identified obstacles, the study team mapped the relevant policy problem and underlying drivers, the magnitude of the problem, and the most affected stakeholders. Based on this assessment, policy recommendations were formulated, targeting the different problems and drivers as well as the different affected stakeholders.

When devising policy recommendations, the study team considered the impact of new technological developments on both the policy problems and possible approaches to address them. Policy recommendations in this field need to be 'future-proof'.

Finally, the draft policy recommendations were accompanied by a draft action plan to implement the different options; particular attention was paid to actions to be undertaken at the EU or national level. The action plan also considers the preliminary achievements of the two pilots and the best way forward.

Consultation activities with stakeholders, consisting of a Delphi survey, were carried out between June and August 2020 in order to refine the policy recommendations and the action plan.

Additionally, during the fourth workshops, the study team presented a selection of draft policy recommendations that support data sharing in the automotive and healthcare sectors. The presentation was part of a wider strand of work focused on identified regulatory barriers and market deficiencies affecting data sharing in the automotive sector, as well as develop policy recommendations to address the identified issues. In a short poll launched during the presentation, the participants were asked to choose one or more draft recommendations they deemed necessary to implement urgently in order to support data sharing in the fields.

The two reports containing recommendations to the EU and national policy makers in the fields of automotive and healthcare will be available soon on the Study webpage.

4.6 Report informing policy actions in the area of skills in the automotive sector – WP1

The Report, which **informs policy actions in the area of skills** focusing on the automotive sector, aims to provide insights on a set of required capabilities and economic and technical competences needed in order to modernise and develop the European market.

In order to study the state of play of existing skills for in-vehicle data of connected and automated cars and inform the Blueprint for sectoral cooperation on skills, the following research activities are planned: 1) gathering of information through an **open discussion** during the third workshop, 2) collect expert opinions thorough a survey to be distributed to approximately 20 experts, and through **in-depth interviews**.

This report informing policy actions in the area of skills in the automotive sector will be available soon on the Study webpage.

5 Final Conference

5.1 Objectives and programme of the Final Conference

The Final Conference's main objective is to present the **results of the pilots to the participants**. In the morning session of the conference, a speech will be delivered by a **high-level representative of the European Commission** who will summarise the objectives and goals of the study. The EU vision and strategy on secondary use of data will also be presented. Following this presentation, an **expert from outside the EU** will present different approaches for handling data sharing and pros and cons from the different approaches.

Then, a **senior member of the study team will make a presentation on the Shared Server in the automotive sector**, which is a workable data platform for undistorted sector development by innovative and efficient service provisioning. A **technical presentation will follow on big data and digital platforms in the healthcare sector**, with a demonstration and interactive presentation. The main findings of the market analysis[12] and policy reports developed throughout the study will be described.

In order to engage participants in the discussion, a **question and answer** (Q&A) session will follow, allowing all event participants to contribute to the discussion and address questions to the consortium experts. The topics that will be discussed during the Q&A session are essentially the following

- The most important lessons learned from both sectors;
- Data sharing facilities in EU - policies must support further openness/exchange of data;
- How to make policy recommendations more concrete, incentives/penalties; and
- Suggestions for future actions, what do participants think of this? What solutions do they envisage?

After the lunch break, a recap and summary of the morning's discussions will be presented. This presentation will then be followed by a **panel session** with high-level experts who will provide an overall assessment of the project based on a mix of important background data and content expertise

[12] Market analysis of the potential of European B2B platforms and unified European diabetes-related data sets

to finally present ideas and recommendations for future action and research. A Q&A session will be held, allowing participants to interact with the panel members and ask questions.

Finally, the conference will end with a session on next steps, in particular on how these types of studies are useful to inform the European Commission on future policy strategies and actions.

We would like to take this opportunity to thank you for your participation in this important study.