Overview of MEDIATOR recommendations legal and regulatory aspects

Deliverable D4.5 – WP4 – PU

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 814735.

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Work package 4, Deliverable D4.5

Please refer to this report as follows:
Fiorentino, A., Ahlström, C., Anund, A., Beggiato, M., Borowsky, A., Busiello, A., Cleij, D., Karlsson, J., Knauss, A., Thalya, P., Toffetti, A., van Grondelle, E.D. (2023). Overview of MEDIATOR recommendations legal and regulatory aspects, Deliverable D4.5 of the H2020 project MEDIATOR.

Project details:	
Project start date: **Duration:** **Project name:**	01/05/2019 48 months MEDIATOR – MEdiating between Driver and Intelligent Automated Transport systems on Our Roads
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	This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 814735.

Deliverable details:	
Version: **Dissemination level:** **Due date:** **Submission date:**	Final PU (Public) 30/04/2023 30/04/2023

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Revision history

Date	Version	Reviewer	Description
15/02/2023	Individual chapters	Mariarosaria Busiello – CRF, Italy	Integration – Editing
29/03/2023	Preliminary draft	Anita Fiorentino – FCA Italy	Task internal review
04/04/2023	Draft for review	Ernst Verschragen – SWOV Institute for Road Safety Research, The Netherlands	Internal QA review
19/04/2023	Draft for review	Ann Williamson - University of New South Wales	External QA review
30/04/2023	Final draft	Ernst Verschragen (QA officer) – SWOV Institute for Road Safety Research, The Netherlands	Final revisions and checks
30/04/2023	Final deliverable	Michiel Christoph (Technical project coordinator) – SWOV Institute for Road Safety Research, The Netherlands	Approved

Legal Disclaimer

Table of contents

List of abbreviations and acronyms

AD	Autonomous Driving
ADS	Automated Driving System
AI	Artificial Intelligence
ALKS	Automated Lane Keeping Systems
AV	Automated Vehicle
DMS	Driver Monitoring System
DSRX	Driver State Recommendation number X
ERC	Ethics Review Committee
GDPR	General Data Protection Regulation
HMI	Human Machine Interaction
HMIRX	Human Machine Interaction Recommendation number X
MIT	Ministry of Infrastructure and Transport
OEM	Original Equipment Manufacturer
ODD	Operational Design Domain
PPAI	Privacy – Preserving AI
SAE	Society of Automotive Engineers
Tier 1, 2, *	Automotive Industry supply chain to the OEM
WoOz	Wizard of Oz
UNECE	United Nations Economic Commission for Europe
VARX	Vehicle Automation Recommendation number X
VTRX	Validation Test Recommendation number X

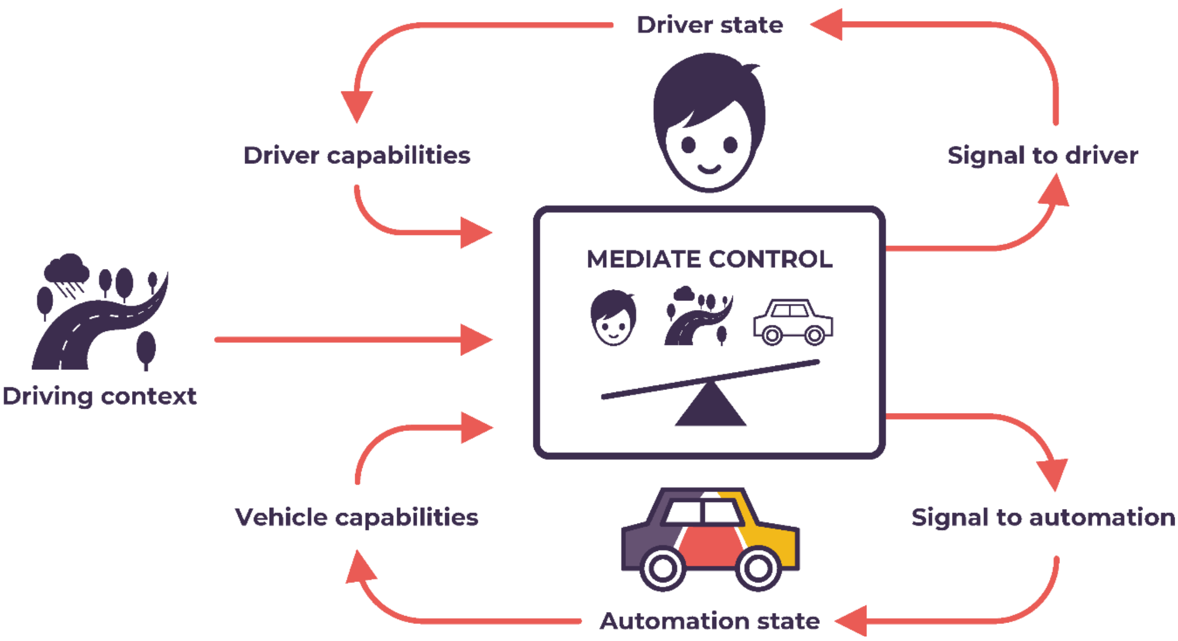
About MEDIATOR

MEDIATOR, a 4-year project coordinated by SWOV Institute for Road Safety Research, has come to an end after four years of hard work. The project has been carried out by a consortium of highly qualified research and industry experts, representing a balanced mix of top universities and research organisations as well as several OEMs and suppliers.

The consortium, supported by an international Industrial Advisory Board and a Scientific Advisory Board, represented all transport modes, maximising input from, and transferring results to aviation, maritime and rail (with mode-specific adaptations).

Vision

Automated transport technology is developing rapidly for all transport modes, with huge safety potential. The transition to full automation, however, brings new risks, such as mode confusion, overreliance, reduced situational awareness and misuse. The driving task changes to a more supervisory role, reducing the task load and potentially leading to degraded human performance. Similarly, the automated system may not (yet) function in all situations.



The Mediator system will constantly weigh driving context, driver state and vehicle automation status, while personalising its technology to the drivers' general competence, characteristics, and preferences.

The MEDIATOR project aimed to develop an in-vehicle system, the Mediator system, that intelligently assesses the strengths and weaknesses of both the driver and the automation and mediates between them, while also taking into account the driving context. It assists the timely take-over between driver and automation and vice versa, based on who is fittest to drive. This Mediator system optimises the safety potential of vehicle automation during the transition to full (level 5) automation. It would reduce risks, such as those caused by driver fatigue or inattention, or on the automation side by imperfect automated driving technology. MEDIATOR has facilitated market exploitation by actively involving the automotive industry during the development process.

To accomplish the development of this support system MEDIATOR integrated and enhanced existing knowledge of human factors and HMI, taking advantage of the expertise in other transport modes (aviation, rail and maritime). It further developed and adapted available technologies for real-time data collection, storage and analysis and incorporated the latest artificial intelligence techniques. MEDIATOR has developed working prototypes, and validated the system in a number of studies, including computer simulation, virtual reality, driving simulator and on-road studies.

With MEDIATOR we further paved the way towards safe and reliable future vehicle automation that takes into account who is most fit to drive: the human or the system.

https://mediatorproject.eu/

Executive summary

This public Deliverable report describes regulatory instruments to test systems like Mediator and provide recommendations for working at European level, within the framework of existing laws and regulations for testing vehicles as levels of automation increase.

The current deliverable is part of the MEDIATOR Impact and Recommendations activities and aims at providing recommendations for working within the framework of existing laws and regulations - as well as adjusting this framework to better reflect the changing functional and logical requirements for vehicle testing as levels of automation increase.

The overall objective of MEDIATOR was to develop an intelligent, self-learning support system, based on in-depth knowledge on human factors, to mediate between human driving and automated driving in the SAE Levels 0 to 4, and have a working prototype ready and validated in a number of simulator and on-road use cases with different user groups. This mediator system will help to realise the potential safety benefits of vehicle automation and therefore to reduce road accidents.

A brief orientation of the Mediator system, what it is, its constituent modules and functions as well as the Mediator key concepts are provided.

This report also contains knowledge and experience gained throughout MEDIATOR's lifecycle that were collected using a questionnaire that was sent to all MEDIATOR participants, to discover root causes of problems that have occurred in the past and to avoid these problems in later project stages or future projects like MEDIATOR. Recommendations referring to the whole MEDIATOR project, the development of the Mediator system and the driving simulator and on-road tests, are also provided. In addition, a web survey was developed to receive suggestions from external experts about possible recommendations for working within the framework of existing laws and regulations at European level, as well as at national level.

Based on the collected lessons learned and web survey results, a total of 18 recommendations are discussed for potential policy changes that could improve the current regulatory framework: eight are related to driver state detection systems, three are related to HMI design, three are related to vehicle automation, and four are related to validation tests. These recommendations should ensure a better safety transport culture and propose improvements to policy makers for the next generation of higher-level vehicle automation.

1. Introduction and general considerations

This introductory chapter contains a summary of the MEDIATOR project, emphasising the key concepts and the modules of the Mediator system, and the project's results in terms of driving simulations and prototypes. The description of the content of each chapter is also reported.

1.1. MEDIATOR overview

The MEDIATOR project is divided in four phases: analysis, design, evaluation and impact. In the first phase literature research in combination with driving simulator, computer simulation and on-road studies were done to establish a set of functional and technical requirements for the Mediator system. As a first step three automation modes and ten use cases under which the Mediator system would be tested were defined. The automation modes were defined from a human perspective, where the human either has a continuous monitor and/or control task, needs to be ready for take-over in the order of seconds, or could be out of the loop completely and even fall asleep. The ten use cases included safety related scenarios, such as transfer-of-control to the human when automation is no longer available, mitigating degraded driver fitness or comfort related scenarios, such as actively proposing a take-over when automation becomes available. Further studies into challenges related to these use cases resulted in a set of functional and technical requirements for the Mediator system.

These requirements were used in the design phase where several lab and in-vehicle prototypes were developed. The prototypes included two driving simulators, one computer simulation, one virtual reality and two on-road prototypes where the Mediator (sub)system was integrated.
In the evaluation phase these prototypes were used to evaluate specific parts of the system under selected use cases in both simulator and on-road experiments. One of the on-road prototypes was used for evaluations in both Italy and Sweden, which was a source for additional legal and regulatory challenges.

Finally, in the impact phase, the evaluation results in combination with knowledge obtained from additional (stakeholder) workshops and interviews were used to perform a safety impact assessment, set up general guidelines for Mediator subsystems and lab testing and introduce a roadmap for further exploitation of the MEDIATOR project results.

The Mediator system has several key concepts that each address a different challenge for current and future automated vehicles. To improve road safety, it is beneficial to let the most capable driver, either human or automation, drive. Who is fittest to drive, however, depends on many aspects such as context and the state of the human driver. Mediator uses input from the driver and automation state monitoring systems, in combination with context information, to determine who is fittest to drive at each moment during a trip. Not only monitoring, but also predicting automation and driver fitness in the near future is needed to, for example, provide ample time for take-overs. To support the driver in self-regulating their behaviour during the different automation modes and to support mode awareness, not only the current automation mode is communicated through different channels, but also the time left in a certain automation mode and the upcoming highest automation mode.

Another challenge in driving in general, and in particular when a driver only has a monitoring task, is to maintain a sufficient level of driver fitness when no higher levels of automation are available. To this end, the Mediator system is designed to initiate corrective actions that mitigate degraded driver fitness due to for example distraction or fatigue.

A final key concept relates to increasing automation use to improve driver comfort and safety during a trip. To achieve this, the Mediator system is designed to actively propose handovers to automation when, for example, degraded driver fitness is detected and a higher level of automation is available or when a higher level of automation first becomes available.

The Mediator system designed in this project consists of five modules: the decision logic, driver state, automation state, HMI and context modules. In Figure 1.1 these modules are shown in relation to the overall Mediator system diagram.

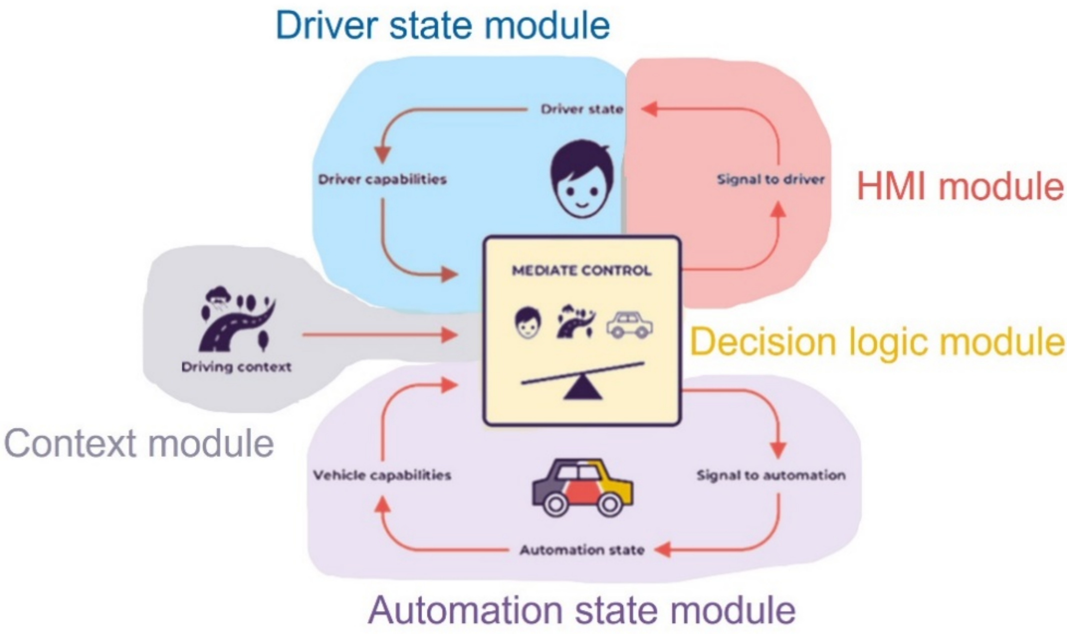


Figure 1.1 Overview of Mediator system modules.

The decision logic module contains algorithms to decide on who is fittest to drive and which actions to take to improve driver safety and comfort during a trip. To make this assessment it uses input from the driver state, automation state and context modules.

The driver state module estimates current (driver monitoring) and predicts near future driver states related to driver fitness and comfort. During the project, driver monitoring systems based on video and physiological data were assessed in both simulator and on-road experiments.

The automation state module estimates the current and predicts the near future fitness related states of all automation modes. To determine current fitness, internal key performance indicators of the vehicle automation are used. To predict automation fitness in the near future, Mediator mainly uses information from the context module. This module provides data on the driving context such as navigation, High Definition map and weather information.

Decisions made by the decision logic module are communicated to the driver via the HMI module. This module makes use of ambient lighting to communicate automation mode, provides multimodal (auditory, visual, haptic) warnings and notifications and uses Light Emission Diodes bars and specialized icons to communicate automation time budgets and upcoming automation level.

The Mediator system was integrated in different prototype platforms. Two driving simulators were equipped with simplified versions of the Mediator system to evaluate comfort scenarios and measures to maintain driver fitness, respectively (Borowsky et al., 2023). Furthermore, a computer simulation including real world data was used to evaluate the decision logic module and a virtual reality study was performed to assess the effectiveness of distraction warnings (Athmer et al., 2022). One on-road prototype was equipped with a close to complete Mediator system, with real-time decision logic and driver and automation state monitoring, but a simplified version of the Mediator Human Machine Interface (HMI) and operating only under manual and assisted driving conditions. A second on-road prototype was instead equipped with the full HMI and real time driver state monitoring, but a simplified decision logic and simulated automation state module. In this vehicle, the automation state module output was simulated based on Global Positioning System coordinates and the automation itself was operationalized using a Wizard of Oz set up (Fiorentino, et al., 2022).

The prototypes were used to evaluate (parts of) the Mediator system. Results from the simulator and on-road studies showed that the Mediator system was generally well accepted and participants expected to use the system if it was available. The Mediator features related to providing time budget information and actively proposing take overs were highly appreciated and the Mediator warnings were shown to effectively reduce distraction.

Results from an on-road study showed that the Mediator system could not only successfully extract information about the current automation fitness, but also accurately predict automation fitness in the near future in real-time and under real world conditions. Furthermore, an on-road study at an earlier stage in the project showed that prediction of human fitness in the near future in terms of fatigue should take into account automation mode, as fatigue development can differ between automation modes. Finally, the evaluations of the decision logic module in both computer simulations and an on-road study showed that the decisions can be made in a comfortable and safe manner, e.g., ample time for safe take-overs can be planned and the frequency of switching between modes is appropriate.

Results from the different evaluation studies were used to assess the potential safety and social impact of the Mediator system if it were to be implemented in future automated vehicles. This assessment showed that significant safety and social benefits could be obtained due to, amongst other, increased automation usage and decreased distraction. Furthermore, the results from the evaluation studies, previous studies within the MEDIATOR project and interviews with stakeholders and industry were used to set up guidelines for designing driver state monitoring systems and human machine interfaces and a protocol for performing low-cost laboratory testing (Fiorentino et al., 2023).

1.2. Main aim and structure of the deliverable

Existing regulations at European and national level aim to safeguard road traffic safety taking human factors and vehicle testing at increasing levels of automation into consideration. To achieve that, there is a need for harmonization.

The main aim of the deliverable is to evaluate relevant strategic and regulatory instruments and to provide recommendations for working on such a complex system with a European consortium, within the framework of existing laws and regulations as well as for adjusting this framework to better reflect the changing functional and logical requirements for vehicle testing as levels of automation increase. According to this, the deliverable examines the regulatory environment within Europe in which technology like Mediator is being developed and to highlight positive and negative aspects and to make recommendations for modifying the framework to accommodate the growing needs for evaluation of new technologies for vehicle automation, either partial or full.

Obviously, only the regulatory and legal issues encountered in developing and testing technologies like Mediator during MEDIATOR project have been considered. The consortium partners are aware that there are other legal and regulatory issues to address to ensure that technology like Mediator is safe and functions as expected technically and by the user when in real use (i.e., recovery actions in case of system fault, responsibility, etc.). These aspects are foreseen in the exploitation roadmap for road transport (Fiorentino et al., 2023).

As automated vehicles are required to be safe, respect human dignity and personal freedom of choice, ethical issues are an important topic for automated mobility. A description of the ethical issues faced in testing the Mediator system is given in Chapter 2.

The existing regulation framework at international, EU and local levels has been investigated and recorded in Chapter 3. In particular, the active regulations for testing systems like Mediator in real road conditions is explained. Examples from Italy and Sweden are also reported.

Chapter 4 describes knowledge and experience gained throughout MEDIATOR's lifecycle, which were collected using a questionnaire that was sent to all MEDIATOR participants. The questionnaire helped to collect the lessons learned during the project lifecycle, focussing on the enablers and the inhibitors encountered during the different tasks. A significant number of issues were encountered in doing this and multiple work-around type decisions were made to achieve the intended outcomes. Suggestions were also given for future projects similar to MEDIATOR, in order for them to avoid negative factors or to apply positive ones learned.

A web survey, described into Chapter 5, was developed to collect practical recommendations that should support the transfer of best practice within the EU and in neighbouring countries and ensure a better safety transport culture as well as to propose improvements to policy makers for the next generation of higher-level vehicle automation.

Recommendations, with a correlation to Mediator system, are provided in Chapter 6. Recommendations should help further exploitation of the potential safety benefits of the Mediator system and similar support systems as well as adjust the framework of existing laws and regulations to better reflect the changing functional and logical requirements for vehicle testing as levels of automation increase.

2. Guidelines and procedures for complying with ethical issues encountered within MEDIATOR

This chapter describes the ethical issues faced in testing the Mediator system. Evaluation of the Mediator system required on-road and laboratory tests involving volunteering participants and data collection. Guidelines were developed within MEDIATOR and procedures were maintained, guaranteeing that the ethical requirements related to participants were met. These guidelines and procedures are also described in this Chapter.

The development of the Mediator system involved various chronological stages, from defining the requirements to building it and evaluating its performance on various platforms. All stages of the project required on-road and lab experimentations involving volunteering healthy adult participants and data collection. In the first few months of the project, guidelines and procedures were developed, guaranteeing that the requirements related to participants' mental and physical safety, their privacy, and data protection were met. Procedures were based on European regulations such as the General Data Protection Regulation (GDPR) as well as relevant national regulations and guidelines. Checklists were also developed, ensuring that all aspects of the subject's participation (recruitment, tasks, information, rewards etc.) were ethically permissible, that data collection and storage plans complied with privacy standards, and that the informed consent forms contained complete and correct information written at a level that could be understood by all subjects.

2.1. MEDIATOR's ethics review committee (ERC)

The MEDIATOR ethics review committee (ERC) was established at the beginning of the project as a result of the strategic decision that all experiments, regardless of the platform, should be ethically approved by a committee with knowledge and expertise to ensure the privacy and safety of the participants was maintained. The ERC began its work by distinguishing between partners associated with organisations that had an internal ERC and partners that did not have an internal ERC. For partners with an internal ERC, the MEDIATOR ERC determined that they should seek ethical approval from their own ERC according to the institutes' procedures and that they should submit their ethical approval to a designated project repository, without the need for any other documentation. For partners without an internal ERC, the MEDIATOR ERC established a process where partners had to fill out various forms generated by the ERC, ensuring these partners followed the same procedure and provided the same necessary information. The filled-out documents were uploaded to the project repository (see Appendix A - Ethics submission forms, for templates of required forms). The ERC read all documents and either approved the ethical request or asked for further clarifications and information. The first evaluation took about three weeks, followed by an additional period of time if any other information and clarifications were needed.

Within MEDIATOR the following general rules and procedures applied:

- No experiments would be conducted without a valid ethics approval.

- All activities would comply with the GDPR and the MEDIATOR Data Management Plan[1].
- No experiments involving minors (younger than 18 years-old) would be conducted.

In case the institute of the project leader had its own ERC:

- The internal procedures for ethical approval would be followed
- After approval by the internal ERC, the project leader was responsible of informing in writing the MEDIATOR ERC that the study had been approved
- In addition, a copy of all original documents had to be submitted to the MEDIATOR ERC and uploaded to a designated project folder.

In case the task leader's institute did not have an internal ERC:

- The applicant had to prepare the following documents (Appendix A) and to upload them to the MEDIATOR internal website:
    - main application form for ethics approval (Appendix A-A.1), English
    - informed consent form (Appendix A-A.2), both in English and origin language
    - research protocol (Appendix A-A.3), English
    - participant Information sheet (Appendix A-A.4), both in English and origin language
    - document with additional information organised in the following sub sections (Appendix A-A.5), English:
        - description how to ensure that participants had the capacity to understand what it meant to take part in the project and to give consent
        - (if relevant) incidental findings policy or a written risk analysis for incidental findings. For example, if a certain system (e.g., ACC) was found compromising the participant's or other road users' safety, how would it be handled?
        - details and methodology to anonymize personal data
        - (if relevant) Clarification of dissemination activities of footage with experiments of human participants. Any release of such a footage should have gotten the participants' explicit acceptance by having them sign the informed consent form that they allowed it. Licence plates should be hidden or always blurred. If video images were released, clarification on the exact type of Creative Common (CC) licence was needed.
        - details on safety measures for any research activity involving on-road studies. For example, how did the task leader make sure that the experimenters and test drivers were safe? For on-road studies, the MEDIATOR ERC focused on features such as chosen routes, time of day and traffic density, as well as general and country-dependent legal considerations. These details were provided along with the research protocol (Appendix A-A.3).

2.2. Field studies for Mediator system testing

Since the Mediator system is a prototype including multiple subsystems, testing the system included on-road studies and laboratory (driving simulator) tests studies. For partners who did not have an internal ERC and submitted their ethics application to the MEDIATOR ERC, on-road studies required the application of additional ethics regulations, some of which were specific to the country conducting the on-road experiment. The relevant partner was responsible for providing all the necessary documentation associated with ethical regulations for conducting an on-road study. This included vehicle testing safety risk assessment focusing on potential hazards and risks associated with the on-road evaluation of the Mediator system, their severity, control measures to

1. MEDIATOR Data Management Plan outlines the data that will be collected and generated during the project, how it will be stored and managed and the measures taken to ensure it will be discoverable, accessible, assessable, intelligible, usable and interoperable. It also describes the relevant data security and ethical aspects.

mitigate the risks, and who was responsible for handling the risk. In addition, each partner involved in the on-road study had to obey the specific national regulations for conducting the studies. Regulations could include, but were not limited to, allowed routes and time of day, type of participants (e.g., professional drivers, employees), driving speed, data privacy protection procedures, etc.

2.2.1. Experiment forms

In addition to the specific regulations for on-road studies, all ethics submissions to the Mediator ERC by members without an internal ERC, had to provide complete details about the experiment by filling out the following items:

1. The experimental procedure and protocol form
2. Information sheet including a description of the study and its purpose to the participant
3. The main form including ethics-related information such as whether deception was involved, how project leaders guarantee participants' data protection and privacy, debriefing of participants, how participants were recruited, participants' compensation, etc…
4. Consent form, that included all information about the study; each participant had to sign the form before being allowed to participate
5. Additional information form, that included additional details regarding video footage data anonymization, etc.

All forms are included in Appendix A.

2.3. Data protection

The MEDIATOR project relied on developing a well-defined data management plan. A data management plan was developed in the first six months of the project. The plan described all data to be collected throughout the project and how it should be handled during and after the project. In terms of data security and ethical aspects, the data management plan included:

1. data types and formats
2. intellectual property
3. access and data sharing
4. resourcing
5. short-term storage
6. deposit and long-term preservation

In today's data-driven world, it becomes more and more important to ensure the privacy of citizens and to secure data from data breaches. This has been anchored in the General Data Protection Regulation (GDPR), which came into force on the 25th of May 2018. MEDIATOR has undertaken various measures to comply with the GDPR as follows.

2.3.1. Data Protection Officers

Ten of the twelve MEDIATOR consortium partners were collecting data through their activities within the project. Each of these beneficiaries had appointed a data protection officer and made the contact details of the data protection officer available to all research subjects involved in their research. In case of a data breach that may pose a risk to research subjects, it was determined that the concerned data protection officer would notify the project coordinator and the affected individuals without undue delay, but in any case, within 72 hours.

2.3.2. Limiting access to and use of sensitive data

Each beneficiary within MEDIATOR had established policies and procedures to limit access to and the use of sensitive data and to protect the fundamental rights of the research subjects. Each beneficiary had to keep the collection and use of personal data to a minimum. If personal data was processed by third parties, it was decided that the MEDIATOR project coordinator would make agreements with those parties before data was collected/sent to the processor. In these agreements third parties were obliged to protect the data sufficiently and to report a breach of data to the project coordinator.

2.3.3. Anonymisation (or pseudonymisation) of data

The laboratory research, surveys, and on-road studies in MEDIATOR did not require pseudonymisation, but all research data sets were completely anonymised. Anonymisation took place immediately after data collection was finished. Some institutes wanted to store participants' names and contact details, and some basic personal information like age and gender, for inclusion in a participant database or for communicating the study's results. This was only possible after the participant explicit consent in writing.

2.3.4. Informed consent

When research subjects were involved, they were asked to sign an informed consent form. This was part of the procedure for ethical approval of all studies with human participants.

3. Regulations for testing systems like Mediator in real road conditions

This chapter presents an overview of existing regulations for testing with automated vehicles in real road conditions. International, EU and local perspectives are furnished along with national examples from Italy and Sweden.

The market for automated vehicles is international, but the regulatory framework differs between countries. The aim with regulations, both for vehicle development and for data collection and evaluations, is to support safe vehicles and safe use (Lundahl, 2022). Despite that, the regulations are not harmonized either in terms of safe vehicles or safe use.

3.1. International perspective

International conventions and agreements are administered by the United Nations Economic Commission for Europe (UNECE). UNECE develops regulations concerning vehicles and road transport through the Inland Transport Committee which is the highest policy-making body in the field of transport. The Vienna convention had, up to 2015, not included Autonomous Driving (AD) and hence considered that “Every driver shall at all times be able to control his vehicle”. From 2016, an amendment was made to accept ADAS, and later also amendments to enable AD were made.

There are two working parties - sub-groups to the Inland Transport Committee - which perform work and have formal decision-making responsibilities related to road traffic and vehicles: The Global Forum for Road Traffic Safety (WP1) and The World Forum for Harmonization of Vehicle Regulations (WP29). Under these, there are dedicated subsidiary working groups or expert groups, for instance: WP1 proposed during 2021 that the driver is “required to respond to a takeover request by exercising dynamic control in an appropriate and timely manner when required to do so by national regulations, traffic rules or guidance; refrain from activity other than driving if that activity may impede this response or is unsafe; and refrain from interfering with the automated driving system in a way that could compromise safety.” In WP1 also the safety vision sets out that the level of safety to be ensured by automated/autonomous vehicles implies that such vehicles shall not cause any non-tolerable risk, meaning that the Automated Driving System (ADS) shall not cause any traffic accidents resulting in injury or death that could reasonably be foreseen or prevented. The WP1 group has worked on amendments to the Vienna convention, but also on a resolution on the deployment of highly and automated vehicles in road traffic adopted in 2018, however not binding. They also work on a resolution on safety considerations for activities other than driving undertaken by drivers when automated driving systems issuing transition demands exercise dynamic control (SAE level 3). They are now working on a new legal instrument for safe use of an Autonomous Vehicle (AV), which will not be implemented within the next five years.

The WP29 (rules on technical requirements) covers the following regulations:

- UN Regulation No. 155 Cybersecurity
- UN Regulation No. 156 Software updates
- UN Regulation No. 157 Automated Lane Keeping Systems (ALKS)

- UN Regulation No. 160 Event Data Recorder

The UNECE Regulation No. 157 on Automated Lane Keeping Systems (ALKS), that was adopted in June 2020, is the regulation most relevant for MEDIATOR. The ALKS regulation is the first regulatory step for automated driving in traffic. It contains administrative provisions for type approval, technical requirements, audit and reporting provisions and testing provisions. In June 2022 an amendment to the ALKS regulation was decided and it entered into force in January 2023 (UNECE, 2022).
The amendment extends the maximum speed for ADS for passenger cars and light duty vehicles up to 130 km/h, and allows automated lane changes, among other dispositions. The ALKS can be activated only under certain conditions on roads where pedestrians and cyclists are prohibited and which, by design, are equipped with a physical separation that divides the traffic moving in opposite directions. In addition, the regulation requires a driver availability recognition system, which control both the driver's presence and availability to take back control of the vehicle. It also automatically needs to suspend the drivers to use onboard devices as soon as the system issues a transition demand.

The Vienna Convention of 1949 and of 1968, as well as the European Agreement for the International Carriage of dangerous goods by road (UNECE, 2021), the 1958 and 1998 agreements on technical vehicle regulations (UNECE, 2017; UNECE, 1998), and the 1997 agreement on periodical technical inspection of vehicles (UNECE, 1997), are crucial. The conventions are the fundamental traffic regulation relevant for the European Union (EU). Since the EU does not have legislation on traffic rules the European Commission has recommended its member states to apply and adhere to the international regulation. The Vienna Convention requires the presence of a human driver who can take control of the vehicle at any time. However, this is about to change to support the use of Automated driving systems.

3.2. EU perspective

On 14 April 2016 at the Informal Transport and Environment Council in Amsterdam, 28 EU Ministers of Transport endorsed the "Declaration of Amsterdam" to work towards a more coordinated approach enabling the introduction of connected and automated driving. Close cooperation between Member States, the European Commission and industry partners is seen as an important prerequisite for the widespread introduction of innovative and interoperable connected and automated driving technologies and services in Europe. The Declaration of Amsterdam on Connected and Automated Driving was an important first step towards a common European strategy in this field and includes a joint agenda for further action to support the shared objectives. Key action points for Member States mainly involve the need to address legal and practical barriers to the testing and deployment of connected and automated vehicles (ERTRAC, 2022).

The EU with the Communication 283/2018 provides a common vision on automated mobility and identifies supporting actions for developing and deploying key technologies, services and infrastructure. "*Driverless mobility promises great benefits but also poses serious questions. In order for automated mobility to gain societal acceptance only the highest safety and security standards will suffice*" (COM 283/2018, page 3). For this reason, the Communication aims to ensure that EU legal and policy frameworks are ready to support the deployment of safe connected and automated mobility, addressing at same time societal and environmental issues, which could be relevant for a public acceptance.

The EU technical requirements and procedures to test AD systems include the following regulations:

- Regulation (EU) 2018/858 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles. The Regulation, in brief, states that:
  - manufacturers shall establish procedures to ensure that series production of vehicles, systems, components and separate technical units remains in conformity with the approved type
  - manufacturers shall examine any complaints they receive relating to risks, suspected incidents or non-compliance issues with the vehicles, systems, components, separate technical units, parts and equipment that they have placed on the market. Manufacturers shall keep a record of such complaints, including for each complaint a description of the issue and the details needed to precisely identify the affected type of vehicle, system, component, separate technical unit, part or equipment, and, in the case of substantiated complaints, manufacturers shall keep their distributors and importers informed thereof
  - the Commission shall organise and carry out, at its own expense, tests and inspections to verify that vehicles, systems, components and separate technical units comply with the relevant requirements. The tests and inspections shall be performed by means of laboratory tests and on-road tests. Manufacturers shall be responsible to the approval authority for all aspects of the approval procedure and for ensuring conformity of production.
- Regulation (EU) 2019/2144 General Safety Regulation amends Regulation (EU) 2018/858 and updates EU type approval requirements to ensure the general safety of vehicles and the protection of vulnerable road users. The main statements are:
  - the vehicle manufacturers should do their utmost to ensure that the systems and features provided for in this Regulation are developed in such a way that supports the driver
  - the functioning of those systems and features and their limitations should be explained in a clear and consumer-friendly manner in the motor vehicle's user instructions
  - safety features and warnings used in assisting driving should be easily perceivable by every driver, including the elderly and persons with disabilities.
- Commission implementing regulation (EU) 2022/1426 for the type-approval of ADS of fully automated vehicles. The Regulation makes executive Regulation (EU) 2019/2144 and furnishes the administrative provisions and technical specifications for the type-approval of the automated driving system of fully automated vehicles. Moreover, the Regulation aims to significantly reduce deaths and serious injuries on European Union (EU) roads by introducing state-of-the-art safety technologies as standard vehicle equipment, and to enhance the competitiveness of EU car manufacturers on the global market by providing the first ever EU legal framework for automated and fully automated vehicles. The scope of the Regulation is, for now, expected to be limited to small series and certain use cases e.g., shuttles of dedicated road, hence not relevant for MEDIATOR.

Of course, also other related regulations like the Regulation (EU) 2016/679, on General Data Protection, are important to consider, as in future systems like Mediator video of the driver's face will be used.

3.3. National regulation for testing

National regulations, that are most often related to trial approvals, differ a lot between countries. Here, the process in Sweden and Italy is described since these are the two countries where data collection took place within MEDIATOR. In general, for systems on SAE L3 the UNECE Regulation 157 on ALKS is the regulation to consider.

3.3.1. Sweden regulation for testing

In Sweden, to test a SAE L4 vehicle on public roads, the Swedish Transport Agency process needs to be regarded (Swedish Transport Agency, 2019). This has been requested since 2017. The process is rather complex as shown in Figure 3.1.

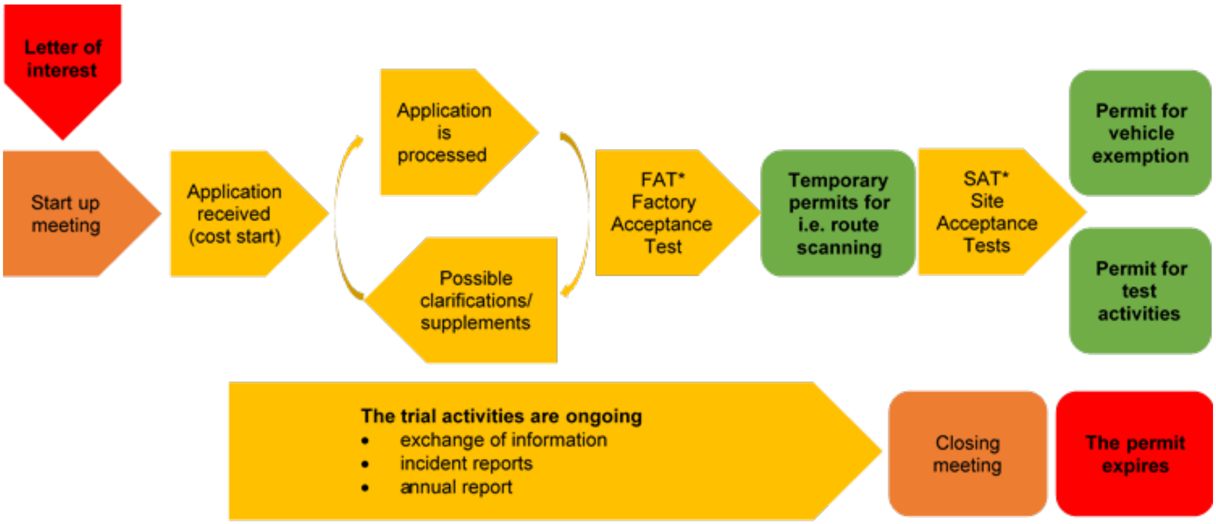


Figure 3.1 The application process in Sweden. (Source: Fürdös, Schallauer, Elpuente, & Flix, 2020).

"In Sweden, every applicant must prove individually, and in great detail, that the trial will be safe. It is important to have a red tread in the application. A common way to organize an application, as reported in Fürdös, Schallauer, Elpuente, & Flix (2020, page 52), is:

Vehicle (ADS + DDT) + Environment (ODD) => Risk analysis => Risk minimization"

Following the description of each term of the above equation.

Vehicle (ADS + DDT)

The applicant needs to provide a detailed technical description of the vehicle including a list of exceptions from the Vehicle Act, i.e., if the vehicle doesn't have a steering wheel, an exception is needed. To get an exception it is required to prove that the vehicle is safe. It is also necessary to describe the Dynamic Driving Task (DDT) and the Automated Driving System (ADS) and their limitations. DDT is about vehicle movements (acceleration, brake, turn left etc.) and ADS is the autonomous technique itself. DDT combined with ADS shall ensure that the vehicle complies with traffic regulations. A factory acceptant test is also required.

Operational Design Domain (ODD)

The applicant needs to provide a detailed description of the environment within which the vehicle will operate, and a description of traffic rules within the testing area. It is also important to talk to the road owner at an early stage. The road owner also knows about traffic accidents in the area and can give advice about road safety.

Risk analysis

The applicant needs to describe how the Vehicle and the Environment fit together. As an example, the description of the vehicle´s ADS shows that the vehicle cannot handle roundabouts and the description of the environment shows a roundabout. This means there exists a risk. The applicant then needs: (i) to assess how serious the risk is, (ii) to quantify the risk under certain circumstances, (iii) to justify the assumption of that risk. For example, the applicant can grade the risk 1-5 (the likelihood of the risk occurring and how serious the risk is). The vehicle cannot handle roundabouts, so the applicant grades the risk equal to 5. If the vehicle cannot handle roundabouts, the risk of someone being injured is very high (5). The applicant is not willing to accept a 5 + 5 risk and something about it has to be done. Another example could be the probability of a meteorite to hit the test site. The risk in this case is equal to 1, but if a meteorite hit the test site everyone will be injured, meaning that the risk is equal to 5. The applicant is willing to accept a 1 + 5 risk in his test.

Risk minimization

The applicant needs to prove that the trial is safe enough. For example, to handle the risk that the vehicle cannot handle roundabouts the switch to manual driving is necessary. But switching to manual driving will raise new safety issues like *how can the interaction between human and machine be safe enough?*

Developing a Safety case is a way to work with risk minimization. In the safety case it is also possible to show how training of drivers/operators are done, how information about safety is distributed within the test group/to the agency, how to act if an accident occurs, who is responsible for what etc.

Alternatives to use are:

- Threat Analysis and Risk Assessment in Automotive Cyber Security
- Hazard and Risk Analysis for the automated system (ISO 26262)
- Safety of the Intended Functionality (ISO 21448:2019).

Site Acceptance Test

A pre-permit test is needed. It is a one-day test with the Swedish Transport Agency to check everything before getting the real permit.

Exchange of information

The applicant also needs to provide information to the Swedish Transport Agency when the permit expires, if an accident/incident occurs, an annual report if the test goes on for more than a year and when the test ends.

The regulation is summarised in Table 3.1.

Table 3.1 Sweden AD legislation.

Item	Description
Regulation (reference)	TSFS 2017:92 (2017-11-01) is the Swedish Transport Agency Regulation on Permissions for Testing of Automated Vehicles (available in Swedish language). It is based on the Decree/Regulation on Testing of Automated Vehicles SFS 2017:309 (2017-07-01 – 2022-07-01) (available in Swedish language).
Scope	Regulation TSFS 2017:92 applies to road traffic with automated vehicles subject to exemption decisions in accordance with Chapter 8, Section 18 of the Vehicle Regulation (2009:211).

Definition	Automated vehicle means a vehicle that has a fully or partially automated driving system. Experimental activity refers to activities involving the use of an automated vehicle to test and evaluate automatic functions not included in a type-approval, individual approval, or registration survey under the Vehicle Act (2002:574).
Potential restrictions	• Experiments with automated vehicles may be carried out only with permission. A licence is valid for a limited period with the possibility of renewal. • Authorisation may only be granted if the applicant shows that traffic safety can be ensured during the attempt and that the attempt does not cause significant disturbance or inconvenience to the environment. A permit decision shall be reviewed if there are special reasons to do so.
Procedure description	Application to the Swedish Transport Agency, which will decide and supervise the testing. Applications shall include, e.g.: • a description of how the testing will be controlled and how responsibilities are distributed • the purpose and objectives of the testing • a description of the automated functions to be tested • a description of how the testing will be performed and evaluated • the geographic area and the streets and roads where the testing will be conducted • a risk assessment.
Authorisation	When the authorisation is granted, the applicant receives a written exemption.
General conditions	When driving an automated vehicle, there must be a physical driver inside or outside the vehicle. A decision on permission to conduct a trial may be combined with additional conditions
Bodies in charge of examining the application for exemption	The Swedish Transport Agency
Special requirements	• The exemption might be accompanied by conditions with the objective of guaranteeing the safety of experiments. • Accidents and incidents are to be reported to the Transport Agency. • A written evaluation of the testing shall be presented to the Transport Agency once a year.
Duration	Not specified
Contact information	The Swedish Transport Agency (Transportstyrelsen): • Phone: +46 771-503 503 • Website: https://www.transportstyrelsen.se/sv/vagtrafik/Fordon/forsoksverksamhet/sjalvkorande-fordon/

3.3.2. Italian regulation for testing

In Italy, tests related to automated vehicles on Italian public roads are regulated by the Smart Road Decree (D.M. 70/2018) issued by the Italian Ministry of Infrastructure and Transport (MIT) with the Protocol n. 70 on February 28th, 2018. The decree:

- fixes functional specifications for the technological components of the main roads; specifications are uniform throughout the national territory
- regulates experimentation on roads open to vehicles with increasing levels of automation and connection
- provides a public observatory to evaluate the effects (and the support) of
  - the digital transformation of the infrastructures
  - the vehicle experimentation and innovation.

The authorisation for experimentation of self-driving vehicles is issued for one or more vehicles, equipped with automatic driving technologies with functional performance able to guarantee an identical level of security on road. Following the authorisation, the vehicles enter in a special register held by the authorising subject and receive a special approval mark for testing. The registration must be displayed both on the front and on the rear of the vehicle during the experimental activity. The vehicles authorised for testing, circulate, during the experimental activity, with test plate released to the senses of the decree of the President of the Republic n. 474 of 2001 (DPR 474/2001). The authorisation refers to the execution of the experiments on one or more road areas and, for each of them, on specific road infrastructures indicated by the subject applicant after obtaining permission from the owner of the road.

Driving on the road of the automated vehicle during the testing, is carried out by a supervisor who: (i) owns, from at least five years, driving license for the vehicle class in test, (ii) has successfully passed a safe driving course or course specifically for self-guided vehicle experimenters, (iii) conducted tests on automatic guided vehicles in a protected area or on the public road, even abroad, for at least one thousand kilometres and (iv) has the documented knowledge to take part in the tests as a supervisor. The supervisor must be able to promptly switch from automatic to manual driving and vice versa. The supervisor has the responsibility for the vehicle in both driving modes.

The manufacturer of the automated vehicle submits to the MIT the application to be authorised to experiment the self-guided vehicle on the road, indicating:

- the owner of the self-driving vehicle
- the road areas for which the request is presented and, for each area, the infrastructural sections on which the trial will be conducted
- the eventual extension of the testing areas referred
- documentation demonstrating the Entity owner of the road authorised the experimental tests, on each infrastructure section required
- the indication, for each proposed road area, of the external, meteorological and visibility conditions as well as the road and traffic conditions.

The declaration, supported by the necessary documentation attached to the application, certifies, under the responsibility of applicant:

- the maturity of the technologies under test related to the road areas for which the authorisation is requested
- the description of the know-how deriving from the suppliers of the components; the test process implemented; description of tests carried out in simulation and/or track, highlighting the deviations from the real application scenarios
- to have already carried out experiments with automated vehicles in the simulation laboratory or in a protected location for at least three thousand kilometres, as well as experiments in laboratory and headquarters protected or on public roads, even abroad, for at least three thousand additional kilometres
- the vehicle capacity, in automatic driving mode, to manage predictable situations in typical driving scenarios (road areas) and external conditions, such as in presence of roundabouts, traffic lights, signals, pedestrian crossings, work in progress, pedestrians, bicycles, animals, obstacles, cones
- the suitability of the vehicle, in automatic driving mode, for each of the considered road areas and external conditions, to implement an adequate reaction referring to the typical driving scenarios and, when not possible, to the possibility of the supervisor of the automated vehicle to promptly intervene maintaining the vehicle in safe conditions
- the description of the technology used for the autonomous vehicle
- the description of the intrinsic safety protections suitable to prevent unauthorised access to automatic guidance systems

- the analysis of the risks associated with the use of the vehicle in automatic driving mode in traffic
- the description of the countermeasures adopted and the safety plans for the test
- the list of the automated vehicle's drivers and the documentation of the training carried out
- the list of the automated vehicles to submit for the experimentation, individually identified, with the indication of the different technological versions applied to each vehicle.

To receive the authorisation to test an automated vehicle on public roads, the system under test must:

- guarantee, in all conditions, compliance with traffic rules as reported in the Italian road code
- be able to interact safely with all possible road users
- allow the passage, in a simple way and in short time, from automatic to manual driving. This suitability is documented in the application for authorisation
- be equipped with intrinsic safety protections suitable to guarantee the integrity of data and the security of communications
- be able, for the entire duration of the tests, to record detailed data with a frequency of at least 10 Hertz including, at least
    - time elapsed since the recording starts (beginning of the experimentation)
    - automatic or manual current operation mode
    - date, time, position in WGS84 coordinates and instantaneous speed
    - instantaneous acceleration
    - distance travelled from the beginning of the trial
    - activation of commands for the lateral dynamics of the vehicle
    - activation of commands for the longitudinal dynamics of the vehicle
    - number of revolutions per minute of the engine, or other equivalent indicator
    - gear ratio engaged, or another equivalent indicator
    - current value of yaw, roll and pitch angle
    - use of lighting and signalling devices both visual and acoustic
    - vehicle to vehicle and vehicle to infrastructure messages received and transmitted.

Authorisation for road tests can be requested referring to one or more of the following road areas, classified according to the Italian road code:

- highways and main suburban roads, characterized by
    - possibility of braking and manoeuvring at high speeds
    - possible work in progress
    - infrequent presence of pedestrians and objects on the road surface
    - controlled and limited access to the ramps
    - possible unstable outflow conditions
- secondary suburban roads, characterized by
    - possible work in progress
    - presence of cycles, motorcycles, pedestrians, animals
    - traffic control systems, such as roundabouts or traffic lights
    - possible traffic conditions characterized by runoff unstable, possibility of queuing at intersections and other phenomena due to saturation runoff conditions
    - uncontrolled access
- urban environment, characterized by
    - possible work in progress, objects or obstacles on the road surface
    - presence of cycles, motorcycles, pedestrians, animals
    - traffic control systems, such as roundabouts or traffic lights

- queuing phenomena, disturbance to the outflow due to activity at roadside, saturated and supersaturated run-off conditions, interference with parking manoeuvres, double-row parking
- uncontrolled access
- speed regulators and speed-controlled zones
- limited traffic areas and pedestrian areas
- parking areas
- intersections without traffic lights
- unpaved roads.

The authorisation for road testing indicates:

- the list of automated vehicles authorised for testing, with the identification of the owner by the chassis number
- the road areas and the related traffic and meteorological conditions
- the list of the automated vehicle's drivers admitted to the road tests.

A copy of the authorisation for road testing must be stored in the vehicle and must be presented to the police officer in case of control.

The authorisation lasts one-year and it can be renewed with a new request by the authorisation holder. During the validity period, the authorisation can be extended, based on a reasoned request of the authorisation holder, if it is necessary to integrate the experimentation with new vehicles, new drivers, new infrastructure sections or new external conditions.

The regulation is summarised in Table 3.2.

Table 3.2 Italian AD legislation.

Item	Description
Regulation (reference)	Smart Road Decree (D.M. 70/2018) of the Italian Ministry of Infrastructure and Transport.

Potential restrictions	• Pilot test authorisation must be requested from OEMs to the MIT.
	• The authorisation refers to the execution of trials on one or more road sections and, for each of them, on specific road infrastructures indicated by the applicant after obtaining clearance from the road's owner.
	• Professional drivers (supervisor) must have:
	  ◦ at least 5 years driving licence, safe driving, or specific courses for such vehicles
	  ◦ at least 1000 km of tests with AD in a protected area or on public roads.
	• Before pilot tests, it is necessary the applicant has already carried out experiments of at least 3000 km with AD vehicles (also vehicles other than those for which authorisation is required) with simulations and tests in a protected location or on public roads also abroad.

Procedure description	The manufacturer of a vehicle equipped with AD technologies submit to the Italian MIT the application for authorisation to test the automated vehicle on the road. The manufacturer must: • require and obtain clearance (Nulla Osta) from the owner of the road for one or more road sections indicated by the applicant • require and obtain authorisation from the Italian MIT, under the advisement of the public observatory. The application for authorisation must contain: • indication of the vehicle's owner • indication of the road areas required for testing and, for each area, an indication of the infrastructural sections on which the experiment will be conducted • documentation demonstrating the clearance to conduct the tests was received by the owner (or management operator) of the road, for each proposed infrastructure section

	• indication of external, meteorological, and visibility conditions as well as conditions of the roads and traffic. It is necessary to attach the following documents: • evidence of the maturity of the technologies that are the object of experimentation • descriptions of the know-how deriving from the suppliers of the components, of the test process being implemented and of the tests that have been carried out in simulation. Possible accidents or anomalies that occurred during the experimentations must be reported and described • documentation that highlights the vehicle's ability to manage predictable situations in typical scenarios of road areas for which authorisation is required and methods for managing the peculiarity of the scenarios; • descriptions of the technology used • descriptions of the intrinsic safety protections designed to prevent unauthorised access to AD systems • risk analysis associated to the use of vehicles in AD mode on the road, descriptions of the countermeasures and the safety plans adopted for the tests • the list of drivers and documentation of the training conducted and the list of vehicles to be tested.
Obligation of the holder of the testing authorisation	To correctly record, during the test: • time elapsed from the beginning of the registration • automatic or manual driving mode • gear ratio engaged. To inform the infrastructure's manager about the program of tests ten days before the beginning of tests. To report events or problems of any nature that involved the system and that may have implications on safety. The report has to be delivered within 15 days from the event, and must contain: • a detailed description of the event • the extract of data collected by the vehicle • any other data recorded by the vehicle, including any video footage. To fill in the annual report on the trials carried out, to be delivered within 30 days from the authorisation's expiration, including the list of the tests carried out. To demonstrate the AD system functionality
Authorisation	When the authorisation is granted, the applicant receives a particular certificate, which is a specific certificate for prototypes for AD experiments.
General conditions	The AD system to test must: • be suitable at all times to allow the transition from automatic to manual driving • guarantee data integrity and the security of communications to prevent unauthorised access • be able throughout the test to record detailed data with a frequency of at least 10 Hz. The documentation must highlight the management methods of the peculiarities of the scenarios. Any accident or anomaly that occurred during experiments, already carried out, both in the laboratory and/or protected areas, must be reported and described.
Duration	The authorisation lasts one year and can be renewed with a new request by the authorisation holder.

4. Lessons learned

This chapter contains the description of the lessons learned of the MEDIATOR project. These lessons learned contain knowledge and experience gained, both positive and negative, throughout the project's lifecycle. These lessons learned also aim to help project teams to discover root causes of problems that have occurred in the past and to avoid these problems in later project stages or future projects.

A questionnaire to capture lessons learned was developed and addressed to the partners involved in the MEDIATOR project. The analysis of the lessons learned highlighted that there was overlap between the interviewees with respect to the enablers and inhibitors that they faced during the project. These commonalities were summarised, together with success factors and possible solutions indicated by the interviewees.

4.1. Methodological approach

Lessons learned contain knowledge and experience gained, both positive and negative, throughout a project's lifecycle. Lessons learned can help project teams to discover root causes of problems that occurred in the past and to avoid these problems in later project stages or future projects. Documenting lessons learned is part of a continuous improvement process. “Collecting positive feedback will motivate team members and make them more confident when tackling other projects. Negative feedback is beneficial too, to help identify what caused hindrances to project deliverables” (Robinson, n.d.).

In particular, main five benefits could be addressed to a lesson learned:

1. Identifying inefficiencies
1. Demonstrating growth to stakeholders
2. Improving communication
3. Streamlining project workflow
4. Improving future decision-making processes.

“By not learning from project failures, the risk is to repeat similar situations. By not maximizing on project successes, opportunities to implement good processes and practices to successfully complete existing and future work could be missed” (Rowe & Sikes, 2006).

A lessons learned process could help to define the subsequent activities required to successfully capture and use lessons learned. The lessons learned process shown in Figure 4.1 includes five steps: identify, document, analyse, store and retrieve.

Figure 4.1 Lessons learned process.

Step 1 of the lessons learned process is to identify comments and recommendations that could be valuable for later project stages or future projects. The main activity for identifying lessons learned is to conduct a lesson learned survey.
The survey will help the participants to focus on the lessons learned during the project and will also give them the opportunity to provide inputs for future projects.
The survey should include specific questions, with in particular the following three key questions:

- What went well? – Not considering positive experiences, could cause proven strategies and opportunities to be missed in future projects.
- What did not go well? – Ignoring what went wrong could cause repetition of the same mistake in the future.
- Were project goals met and if not, why? – Project goals have to be achieved on time. If not, it is necessary to examine the reasons why in order to take preventive action, if possible, and to stop it from occurring in a future project (activity).

Step 2 of the lessons learned process is to document into a report an overview of the project strengths (what went well), project weaknesses (what went wrong), and recommendations (what needs to improve). The report should be organized by key fields and should include responses gathered from the survey participants and should be stored with the other project documentation.

Step 3 of the lessons learned process is to analyse and organize the lessons learned for future application. A brief summary of the findings could be of help to highlight factors of success and possible solutions to overcome project risks.

Step 4 of the lessons learned process is to store the lessons learned in a repository and make them available to other project teams.

Step 5 of the lessons learned process is to retrieve relevant lessons learned for use on current or future projects.

4.1.1. MEDIATOR approach

Following the methodological approach, a lessons learned questionnaire was developed and addressed to partners involved in the MEDIATOR project.

The questionnaire was organised into two sections. In the first section, interviewees were asked to point out the main enablers (what went well) and the factors that supported success, as well as inhibitors (what did not go well) and the solutions adopted. In the second section, five specific open questions were formulated:

1. What were the enablers for the implementation of the Mediator system?

2. What were the inhibitors for the implementation of the Mediator system and what should be avoided or addressed early if similar systems were to be undertaken?
3. How did you deal with regulation inhibitors to reach your specific goals?
4. What unplanned event(s)/activity(s)/circumstance(s) did the team have to deal with?
5. Recommendations for working within the framework of existing laws and regulations.

The lessons learned were synthetised, and the same enablers and inhibitors reported by the interviewees were summarized in the following paragraph, together with the factors of success and the solutions adopted.

4.2. Analysis of the lessons learned

The purpose of the analysis of the lessons learned, filled out by the partners involved in the MEDIATOR project, was to identify actions that could help project managers to strengthen weak areas of knowledge and to implement or avoid those actions in their future projects. The analysis highlighted that it was necessary to make a number of compromises to ensure that the project could be completed successfully.

In the following paragraphs there is a description of the lessons learned divided into four sections:

1. Enablers
2. Inhibitors
3. Events not planned
4. Recommendations

4.2.1. Enablers

The lessons learned have become one of the most important driving forces for project success. They help to find, select, organise, distribute, and transfer relevant project information. The development of lessons learned have led to the need of identifying its critical success factors. The most important enablers that are believed to be critical for effective project implementation can be divided into three groups:

- Global enablers, referring to the enablers related to the whole MEDIATOR project
- Mediator system development, referring to the enablers strictly related to the development of the Mediator system
- Validation trials, referring to the enablers related to the driving simulators and on-road tests.

Global enablers

- Previous experience and knowledge sharing. The prior expertise and knowledge with driving simulators in terms of technology, scenario design, auxiliary systems, metrics such as eye tracking, cameras, HMI, and synchronization of systems, as well as in ethical issues, made it possible to prepare most of the materials even under the COVID-related impossibility to physically be present in the laboratories (e.g., driving simulators, workshops, etc…). These extensive preparations allowed to implement and finalise the whole experiment in a short time (e.g., less than one month for driving simulator test), when the laboratories were opened again for the scientific staff. At the same time, the strong experience in user testing methodology and conducting in different environments, helped to define the procedure for the on-road tests and manage all the organisational and unexpected issues.
- Working in team. In order to design and realise the Mediator components, the working team collaborated from the first phases of the project up to the final period. Weekly status meetings, piloting results, and data were continuously held and shared between the partners to make sure all milestones were met, and the prototype was working as intended for data collection.

The factors of success were the dedicated timeline and responsibilities and the weekly status meetings, sharing piloting results and data.

- Design and industry acceptance. Brand identity could be crucial for market penetration, but the Mediator design allowed OEMs to have the design freedom to create brand-specific variations. There is no Mediator system preference towards the level of control by either driver or vehicle.

Mediator system development

- Modular approach. Functions of the general Mediator concept were modularised in the sense that the development process was set up in such a way that each component team could work on its development relatively independently from the other components. The factors of success were that each MEDIATOR component team could work on its development relatively independently from the other components and develop their own hardware and software solutions mainly in home-office conditions.
- Platform sub teams. The MEDIATOR components were broken down into subcomponents. Small teams were formed on this subcomponent level, which enabled a highly effective and efficient mode of working. It allowed for exploiting the maximum benefit of each evaluation platform/method. The factor of success was that dedicated platform sub teams allowed efficient alignment of technical developments with the experimental study design for each of the platforms. Even though each study had its own specific focus, full coverage of Use Cases and Mediator components was achieved across all studies.
- Central mediation component. The Mediator system has one central component that plays a central integration, decision, and communication role, and interacts with each of the other main components. It also includes centralized driving context and personalisation (sub)components. All information flows go through this component, and also all major Mediator decisions are made within this central component. Having a central mediation component that interacts with all of the other components had the advantage of clear distinct division of organisation's responsibilities and component tasks.
- Central gateway. The Central gateway is a special type of subcomponent within the Central mediation component, whose role it is to act as a communication 'bridge' and 'arbitrator', to allow proper information (message) exchange between all other main components. Having a subcomponent within the Central mediation component allows to have central Application Programming Interface validity and version checks.
- Human Machine Interface development strategy. The HMI design strategy that was followed in the MEDIATOR project was Research by Design i.e., HMI concepts were designed, based on literature studies and design experience (also involving students). Design concepts served as testing facilities to either investigate the HMI as whole, or to investigate specific knowledge gaps. This was organised by a rapid iteration of graduation projects. Advantages of this method are:
    - The involvement of graduation students allowed to design and investigate multiple concepts entering new thinking and new ideas into the design process. Those ideas are either of direct value or help to build a so-called design inventory from which to benefit later.
    - Concept designs for trials and studies enter the project earlier, saving time if compared to the involvement of a PhD candidate who may contribute no earlier than after a year of literature research.
    - Early concept designs and physical installations facilitated the consortium partners to understand the components' integration visuals and movies.
- Availability of more than one driver state solution. The availability of hardware and software to collect driver monitoring data, including different driver states, in real time studies, and the capacity to develop them, were already available within the consortium. The different solutions

enabled new ways of thinking regarding driver monitoring, algorithms and how to use functions within the vehicle system. This also allowed to have backup solutions for real-time driver state. As an example, for real-time driver state monitoring, an additional distraction detection system was installed into the Human Factors in-vehicle prototype.

- Well-defined work methods and procedures. Working with specific forms and templates and well-defined procedures allowed fast handling of ethical requests. A designated protected online storage was created in the project's SharePoint, where all forms and submissions were kept and handled.

Validation trials

- Non-functional Wizard of Oz (WoOz) vehicle prototype. Users appreciated very much to have an "automated" vehicle experience, even if the WoOz vehicle prototype was not functional. After a while they "forgot" there was the professional driver driving the vehicle and interacted with the experimenter as if they were in an automated vehicle. The user testing allowed to identify pros and cons of the Mediator HMI solutions and to advise some redesign guidelines to enhance even more their usability for the next trials.
- Data sharing. Early on, a well-defined data sharing pipeline was planned and implemented during the piloting phase of the in-vehicle prototypes. This resulted in sharing of the data as it was collecting to other partners for analysis, such as for the computer simulation the data collected by the TI in-vehicle prototype were used.
- Clear definition of Use Cases and study focus. An early and clear definition of the study focus including connected Use Cases allowed to evaluate the best test configurations. One of the driving simulator studies, for example, focused on comfort transitions of control from manual to automated driving, simulated automation degradation and related transitions of control by the human driver.
- Equipment and technical support. The state-of-the-art related to the driving simulators with automated driver capabilities and the technical support of mechanical and electrical engineers, allowed to easily integrate complementary systems such as eye tracker, cameras, etc.
- MEDIATOR Ethics Review Committee (ERC). The committee defined processes of who should submit an ethical request and how. For organisations that had their own Internal Review Board, the MEDIATOR ERC requested only approval from the organisational Interna Review Board. For organisations without any internal ERC, the mediator ERC defined a specific procedure with forms to be submitted to the mediator ERC. This procedure facilitated the ethical approval procedure for those organisations.

4.2.2. Inhibitors

The inhibitors are any circumstance that could delay the smooth project development, if not properly managed. Similarly to the enablers, three most important groups of inhibitors were highlighted, and for each inhibitor, solutions adopted or possible solutions on how to manage it are reported:

Global inhibitors, referring to the inhibitors related to the whole MEDIATOR project

- Mediator system development, referring to the inhibitors strictly related to the development of the Mediator system
- Validation trials, referring to the inhibitors related to the driving simulator and the on-road tests.

Global inhibitors

- Partner leaving consortium. One partner ceased to exist and its tasks were handed over to two new organisations entering the project.
  The solution used in the MEDIATOR project was to have a modular approach in the project that could help in realising a smoother hand-over.

- Different skills in the project consortium. A multidisciplinary team is generally a factor of success but can create misunderstandings and difficulties. Developers, HMI designers and experimenters have had different mental models of the demo platforms, their capabilities, and how they should be used to test the Mediator system. This led to a mismatch between the developed prototype and the experimental design.
  The solutions used in the MEDIATOR project were:
  - the development of a common dictionary in advance to overcome language and competence barriers
  - to have smaller dedicated teams for each of the demo platforms
  - to use the same questionnaires and similar metrics
  - to make the organisation responsible for the prototype also responsible for the experiments with it
  - to prioritise the integration and harmonisation of everyone's expectations at an early stage.
- Operational issues. The project activities are strongly linked to each other, which requires a strong cooperation and interaction between the partners, leading to operational issues.
  The solutions used in the MEDIATOR project were:
  - the use of dummy components when wanting to test an individual component while the other components are not yet available
  - to start the planning of different studies for evaluating the Mediator system in advance by a dedicated workshop.
- Industry acceptance. The state of the art of automotive components for automation has progressed rapidly during the years of the MEDIATOR project. Because of this, Mediator implemented solutions could be rejected by the industry.
  As a possible solution, the Mediator system should be more flexible to influence the industry and be open for inspiration from the industry.

Mediator system development

- Dealing with prototype systems. To test the Mediator system (Algorithms, Control Units and sensors), different vehicle prototypes were adapted starting from on-market vehicles. To adapt the new component to an existing vehicle produced unexpected circumstances related to the integration of the system into the vehicle as well as regulatory issues for the testing. Since the demo vehicles were prototypes appositely developed, especially during the lockdown, unexpected circumstances occurred during the tests and it was necessary to manage them generating some delays (i.e., steering wheel malfunction in the driving simulator stalled experiments by two months).
  To overcome this inhibitor the solutions used in the MEDIATOR project were:
  - to maintain documentation of start procedures and troubleshooting to complete the data collection
  - to simplify the instructions to get all systems up and running to avoid complex tasks, where any mistake could lead to a complete system failure
  - to have the redundancy of systems in order to avoid loss of data.
- Shipping of testing vehicle. The plan of shipping the Human Factors in-vehicle prototype from one country where it was built (Italy) to another (Sweden) where the vehicle underwent extensive on-road testing led to both regulatory and technical roadblocks and difficulties. The owner of the Human Factors in-vehicle prototype had to fill in an application for temporary registration/temporary import, get proof of Swedish third parties liability insurance for temporary registration, and perform a motor vehicle inspection test once the vehicle reached Sweden.
  The possible solution for this inhibitor is to start the authorisation process as soon as possible and be flexible in dealing with potential newly arising issues, prioritising, and refining the scope of subsequent work.

- TI in-vehicle prototype. The study setup includes a vehicle that was not modified in any way that would void any critical safety systems and is an approved production vehicle where technical integration of Mediator prototype was carried out. However, due to test vehicle collecting data in the open road, it had a sign stating the information was being recorded, and it was GDPR compliant.
  The solutions used in the MEDIATOR project was an early definition of the study to prepare the detailed ethical evaluation form for the MEDIATOR Ethics Review Committee in time.

Validation trials

- Ethical issues related to run test with in-vehicle prototype. Tests and data collection involving volunteers (within the on-road or driving simulator studies), had to guarantee that requirements related to participants' mental and physical safety, their privacy, and data protection were met. According to this the in-vehicle prototype should not be modified in its safety systems and all activities should be GDPR compliant.
  To overcome this inhibitor, it is recommended to prepare in advance the proper documents and protocol.

4.2.3. Events not planned

The unplanned events that occurred during the project lifecycle, as reported by the interviewees, can be grouped into two sections:

- Global features, referring to events affecting the whole MEDIATOR project
- Validation trials, referring to events affecting the driving simulator and on-road tests.

Global events

- COVID-19. The COVID-19 pandemic hindered cooperation between teams in the project as they were not able to have periodic physical meetings, which usually give a boost to the progress within cooperative work. The pandemic also affected the recruitment of participants for in-place studies and the physical implementation of some technical components. As it was not possible to visit the driving simulator before the study started, only a reduced set of hardware and software components was implemented according to the selected study Use Cases. Restrictions due to COVID (difficulties to operate in the laboratories and workshops) generated time delays in the preparation of the in-vehicle prototypes (integration of new components, preliminary on-road tests, calibration and implementation in real road conditions of the scenario use cases, etc..) for the on-road tests.
  The possible solutions are to use the opportunity to have clear assignment of tasks for each team, strong collaboration and good interaction with colleagues, and online meetings, even if the latter showed some limitations:
  - Meetings that require long attendance, like General Assembly meetings, must be organised differently, for example, with shorter interaction and more and longer breaks.
  - There is limit to the period in which communication can remain to be online. Physical meetings with a social aspect become necessary at some point.
  - Online meetings do not work for creative processes such as concept design workshops. These require physical presence, and physical interaction, like the sharing of e.g., a drawing or prototyping environment.
  - Online communication is difficult in case of conflict mitigation. Conflict mitigation requires less direct communication that allows for nuance. Conflict mitigation also requires social interaction, which does not work in business interaction alone.
  - Online communication is much more difficult between partners that have never met in person, like in the aforementioned on-boarding of new partners. The integration of new partners or people in a consortium that already built a sense of community is also difficult.

- A problem occurs when partners in different countries or companies are being confronted with different regulations. While, as mentioned, physical meetings become important after a longer period of only online meetings, there is a dilemma when not all partners are able or allowed to travel.
- To organise hybrid meetings requires more organisation and often creates an inequality between people present and people online.

Validation trials

- Unplanned roadwork. An unplanned roadwork forced to change the experimental route one week before the experiment started. The implemented standard software procedure in the simplified Decision Logic, allowed to adapt the new route reducing the consequent time delay. The suggested solution is to have a standard (not ad hoc) software development based on, for example, external tables modifiable at request.
- Recruitment of participants. The recruitment of participants was extremely time consuming. It was difficult to find people willing to participate. This was especially true for experiments to study drowsiness that requested the involvement of sleep deprived volunteers. A first solution adopted was to involve night-shift workers, even if the involvement of such a kind of workers was not easy especially because two experimental days into their daily schedule were necessary. To solve this further issue the adopted solution was to adequately compensate for the volunteers' effort (i.e., to pay a taxi to take volunteers at home after trial, to give gift cards, etc.).

4.2.4. Recommendations

The recommendations as suggested by the interviewees were grouped into three sections:

- Global recommendations, referring to the recommendations related to the whole MEDIATOR project
- Mediator system development, referring to the recommendations related to the development of the Mediator system
- Validation trials, referring to the recommendations related to the driving simulator and on-road tests.

Global recommendations

- Collaboration between project partners. Projects like MEDIATOR require a continuous interaction among the partners because the activities are strictly related. The strong collaboration between the partners could help in understanding the development choices and lowering the criticality during the project.
- Common dictionary. The development of a common dictionary could be useful to overcome language and competence barriers that could lead to misunderstandings and difficulties.
- Try to anticipate. To start all processes as soon as possible: this includes for example the specific planning of evaluation study designs with fallback solutions, even if not all details (such as technical capabilities of the system) are already known. The same applies for ethical approval processes as well as organisational issues such as transferring a vehicle to another country. The same is valid to investigate all the possible laws and regulations that have an impact on testing, and to share all findings among partners involved in the task and to agree how to manage them and prepare the proper documents and protocol.
- Flexibility. To be flexible and organise a more complementary work plan with clear separated tasks and regular formal status updates to face unexpected events like COVID-19.

Mediator system development

- A Mediator system should fit within the industry defined standard for assisted and autonomous driving, and it should be flexible to update according to industry vehicle development plans. Vehicle development time covers about 48 months, and during this time all components (new or existing) are developed and integrated into the vehicle architecture, including virtual and on-road validation. To test the Mediator system on the road, it was necessary to adapt it to an on-market production vehicle and ensure the integration of the system into the vehicle as well as regulatory issues for the testing.
- Components fulfilling existing regulations were used in the vehicle validation trials.

Validation trials

- To improve computer simulation studies by training models of user behaviour based on data regarding the behaviour of drivers. For instance, a data-driven estimate of how likely it is that a driver will accept a suggested shift in automation level can lead to improved evaluation of the Mediator decision logic.
- To overcome the strict regulations regarding personal data (GDPR), the solution adopted was the use of clear and transparent informed consent agreements with the participating drivers/subjects, as well as the use of secure regulation-compliant data storage and handling and data sharing.

5. External web survey

This chapter shows the results of the external survey conducted to receive suggestions about possible recommendations for working within the framework of existing laws and regulations at European level, as well as at national level.

The web survey of experts was broad and asked about the impact of the current regulatory framework to work with systems like Mediator, including HMI design and safety of higher level automation systems. It was developed and conducted amongst experts from different fields to learn more about their needs and field of actions related to the specific MEDIATOR domains (driver state detection system; HMI; vehicle automation; validation test), in order to make practical suggestions for improvements in future directives or regulations as well as funding instruments.

The recommendations related to liability and shifts in responsibility between driver and automated system will help in defining the applicability of the Mediator systems.

5.1. Structure of the survey

The web survey was developed to maximise transfer of knowledge to the relevant specific MEDIATOR domains, by involvement of experts from the different related fields. It was divided into five sections:

- Section 1 contained questions on general background information of the respondent. The information requested was:
  - Name of organisation
  - Country
  - Type of organisation
  - Branch(es) of activity
  - Size of the organisation
  - Field of expertise; this question was related to the personal expertise and skills of the participant, which was either in the field of:
    - Driver state detection systems
    - HMI design and Human Factors
    - Vehicle automation (design and software), or
    - Validation tests (simulator and on-road)
- Section 2 was related to the impact of Mediator-like systems with higher-level vehicle automation. The questions included in this section were about:
  - the relevance of the Mediator system implementation with regard to new and EU goals for improving road safety
  - the safety impact of higher-level automation systems in the short term
  - the safety impact of higher-level automation systems in the long term
  - the impact of higher-level vehicle automation systems - independently on the sector of application - in the supply chain
  - the influence of HMI human centred design on higher-level vehicle automation systems
  - any other positive or negative effects of higher-level vehicle automation systems in the participant company, on safety and more in general on sustainable mobility

- Section 3 was related to the funding instruments. There are several funding instruments at national and European level to support research and development projects to improve transport safety through a more timely, focused and integrated adoption of human factors in the design of road or rail vehicles, vessels or aircraft, infrastructure and the mobility system - taking advantage of automation - as well as increasing knowledge of enhanced human machine interactions to further advance the development and use of automation without introducing new, previously unknown, safety risks. The experts were asked about:
  - the quality (i.e., funding volume and rates) of available funding instruments related to human factors in transport safety in the participant's country or sector(s).
- Section 4 was related to the European and national regulations. Existing regulations on European and national level aim to safeguard road traffic safety taking human factors and vehicle testing at increasing levels of automation into consideration. To achieve that there is a need for harmonisation. Since national regulations on trial approvals differ a lot between countries, in this survey only regulations on EU level were considered. The information requested was:
  - the adequacy of current regulations and directives at European level for the development (design and testing) of vehicles with increasing levels of automation
  - the negative or positive contribution of current regulations and directives at European level to the development (design and testing) of vehicles with increasing levels of automation.

  The following legislations were specifically referred to:
    - Commission recommendation 2008/653/EC on safe and efficient in-vehicle information and communication systems
    - Regulation (EU) 2019/2144 (General Safety Regulation)
    - Commission implementing regulation (EU) 2022/1426 type approval of ADS of fully automated vehicles
- In section 5 participants were asked to express practical suggestions for improvements in future directives or regulations, as well as funding instruments, related to:
  - Driver state detection systems
  - HMI design and Human Factors
  - Vehicle automation (design and software)
  - Validation tests (simulator and on-road).

5.2. Analysis of the survey

The survey lasted 15 days and a total of 33 responses arrived from experts in different fields, located in France, Germany, Italy, Sweden and the Netherlands.

5.2.1. Type of organisation

Participants of the survey came mainly from academia and industry (88%) with a higher percentage for industry (52%). Almost all the participants (91%) were involved in activities related to automotive. The organisations the participants came from (both academia and industry), had more than 500 employees (82%).

5.2.2. Field of expertise

Validation tests with simulator and on-road, vehicle automation design and software and driver state detection system (18%) were the main fields of expertise of the participants as shown in Figure 5.1.

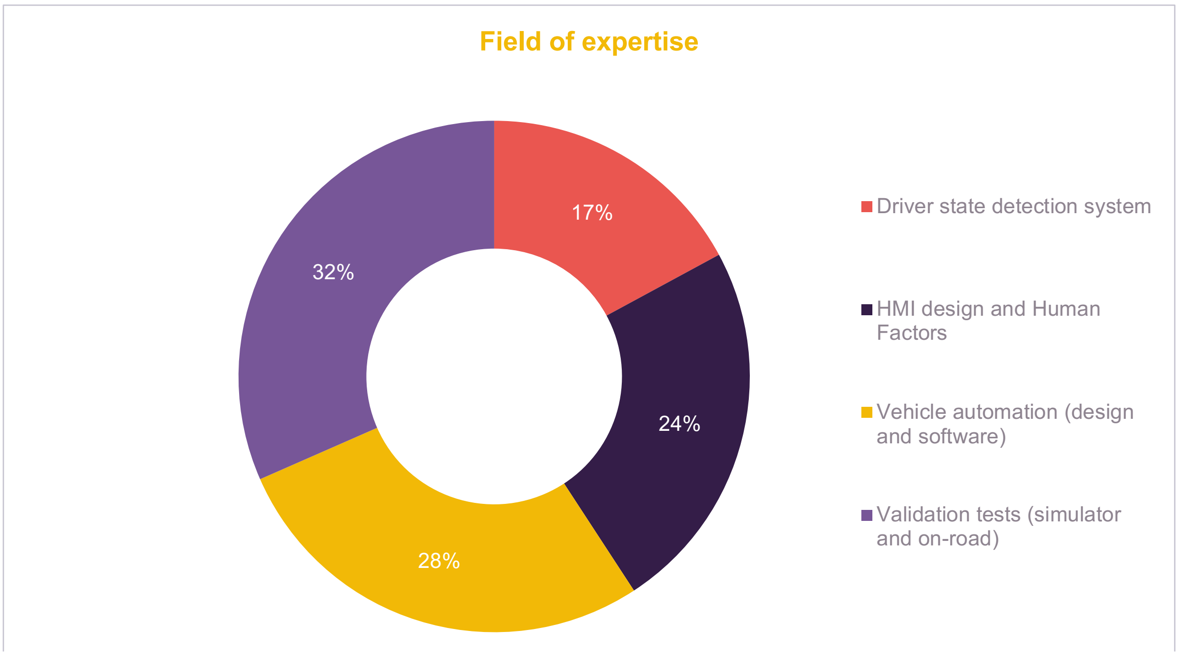


Figure 5.1 Fields of expertise of the participants to the web survey.

5.2.3. How do you rate the relevance of the Mediator system implementation with regard to new and EU goals for improving road safety?

Participants were informed about the benefits of implementing a system like Mediator and were asked to give their opinion about the relevance of Mediator system implementation with regard to new and existing EU goals for improving road safety.
About 80% of participants replied that in a range from 1 (very low) to 5 (very high), the relevance of Mediator system implementation is 4 and 5 (most of them indicating 4 (45%)). It means that, according to the participants, the implementation of the Mediator system could generate high positive impacts on road safety.

5.2.4. How do you estimate the safety impact of higher-level automation systems in the short term?

Participants were asked to evaluate the safety impact of higher-level automation systems, regarding four transport modes (road passenger transport, road freight transport, air passenger transport and railway transport). As reported by the participants, the impact will be moderate in the short term for almost all of the transport modes considered, with a possible high impact for road freight and railway transport (see Figure 5.2).

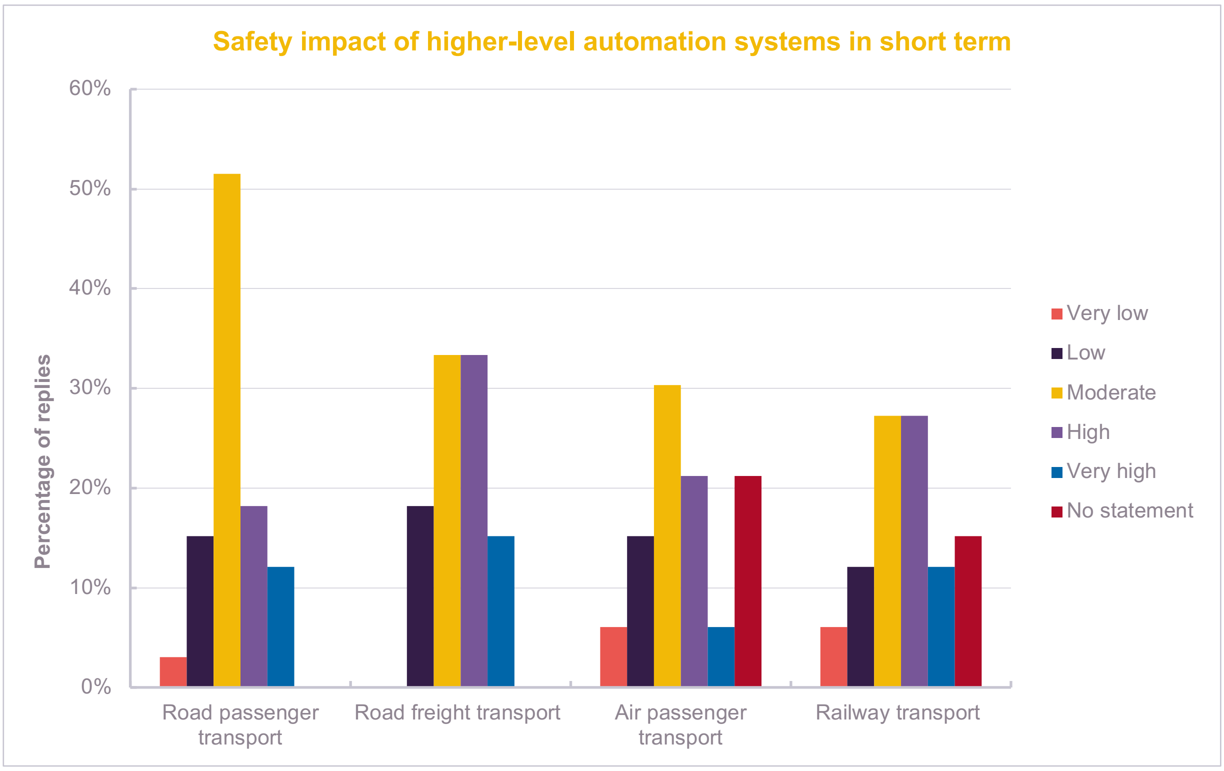


Figure 5.2 Safety impact of higher-level automation systems in the short term.

5.2.5. How do you estimate the safety impact of higher-level automation systems in the long term?

The overall responses paint a picture of optimism about the safety of these systems, especially in the long term. In particular the impact is estimated very high for road (both passenger and freight) transport, moderate/high for the air passenger transport, and high for the railway transport (see Figure 5.3).

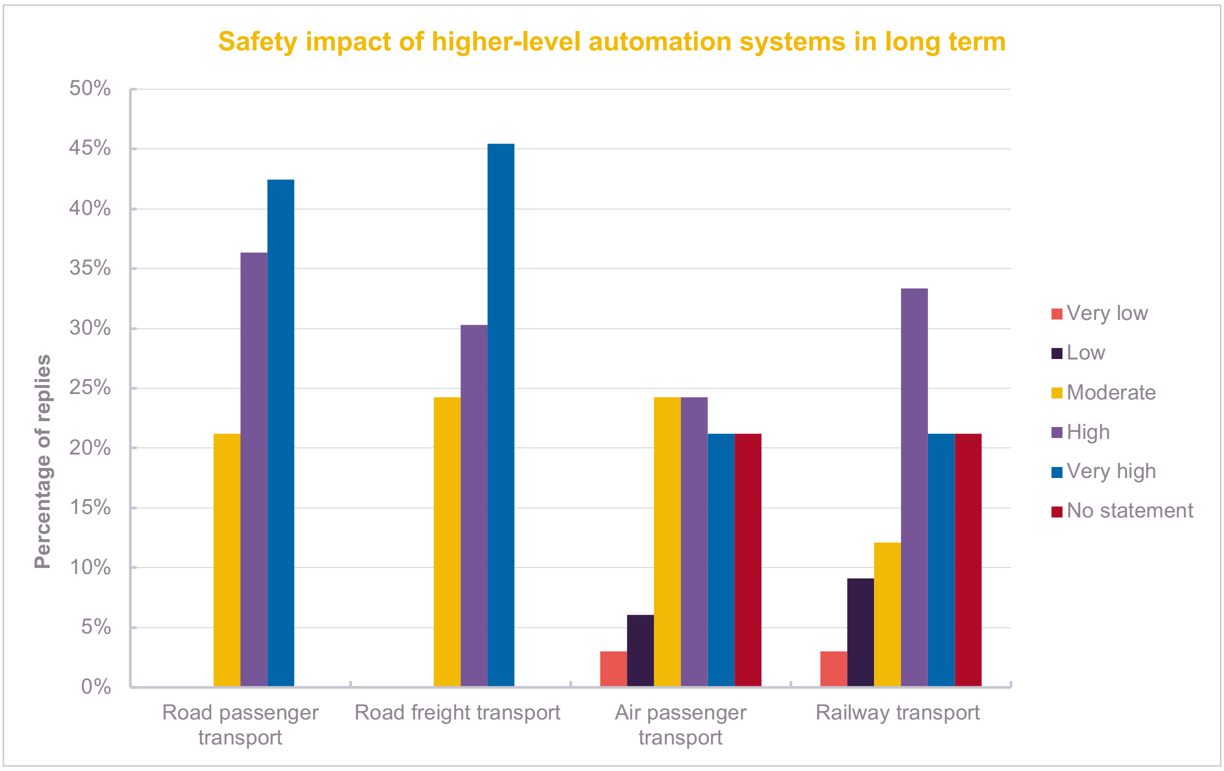


Figure 5.3 Safety impact of higher-level automation systems in the long term.

5.2.6. How do you rate the impact of higher-level vehicle automation systems - independently on the sector of application - in the supply chain?

Participants were asked to express their opinion about the impact of higher-level vehicle automation systems in the supply chain (in terms of, i.e., necessity of new developments of the product from Tier 1 supplier, changes in the usual design approach, necessity to increase the duration of the validation activities, etc…).

58% of participants replied that in a range from 1 (very low) to 5 (very high), the impact is equal to 4, only about 20% of participants stated an impact equal to 3 or 5.

5.2.7. How do you rate the influence of HMI human centred design on higher-level vehicle automation systems?

HMI human centred design is fundamental for the development and acceptability of systems with high level of automation (like Mediator).

In a range from 1 (very low influence) to 5 (very high influence), 55% of participants replied that the influence of HMI human centred design is equal to 4, while for 30% of participants the influence is equal to 5. The result means that for 85% of participants guessed that the HMI human centred design is fundamental.

5.2.8. Do you foresee any other positive or negative effects of higher-level vehicle automation systems in your company, on safety and more in general on sustainable mobility?

Responses, as reported by the participants, were grouped according to positive or negative effects, as follows.

Positive effects

- Higher-level vehicle automation systems will increase efficiency, sustainability and mobility safety, especially considering shared mobility (e.g., the user could book a vehicle that would arrive autonomously at the requested location and, after the usage, it would return to the depot, where it could be recharged, for example, if electric).
- Higher-level vehicle automation systems could produce a reduction of overall number of cars leading to an improvement of citizens' time management and well-being (i.e, less traffic jams, more on highways).
- Checking the state of the driver and passengers, monitoring their vital parameters, with the aim to foresee the occurrence of critical situations (such as, for example, loss of consciousness due to illness or falling asleep due to overtiredness, etc…), will help in avoiding the resulting problems should any of these events occur while a person is driving.
- The automation system will help drivers to drive more safely, decreasing the number of human error.

Negative effects

- AD - especially at higher level - seems to be quite far from market-entry, and L3-SAE AD can cause many problems, even more than the ones that could be solved. Without a proper virtual simulation with driver simulator and human in the loop (i.e., hybrid traffic scenario with driver and driver-less vehicles), the safety assessment will be weak.
- Misuse and disuse of automation by human operators, especially if the automation implementation is not designed considering the human performance, could produce negative effects on safety. Only a deep understanding of the factors associated with the study of user experience and acceptance of automation can lead to improved system design, effective training methods, and safety policies.

5.2.9. How do you evaluate the quality of available funding instruments related to human factors in transport safety in your country or in your sector(s)?

The quality of available funding instruments, at national and European level, to support research and development projects to improve transport safety, was also investigated.
45% of participants indicated that the funding instruments available at national level are inadequate; on the other hand, 55% of participants indicated that the funding instruments available at European level are adequate (see Figure 5.4).

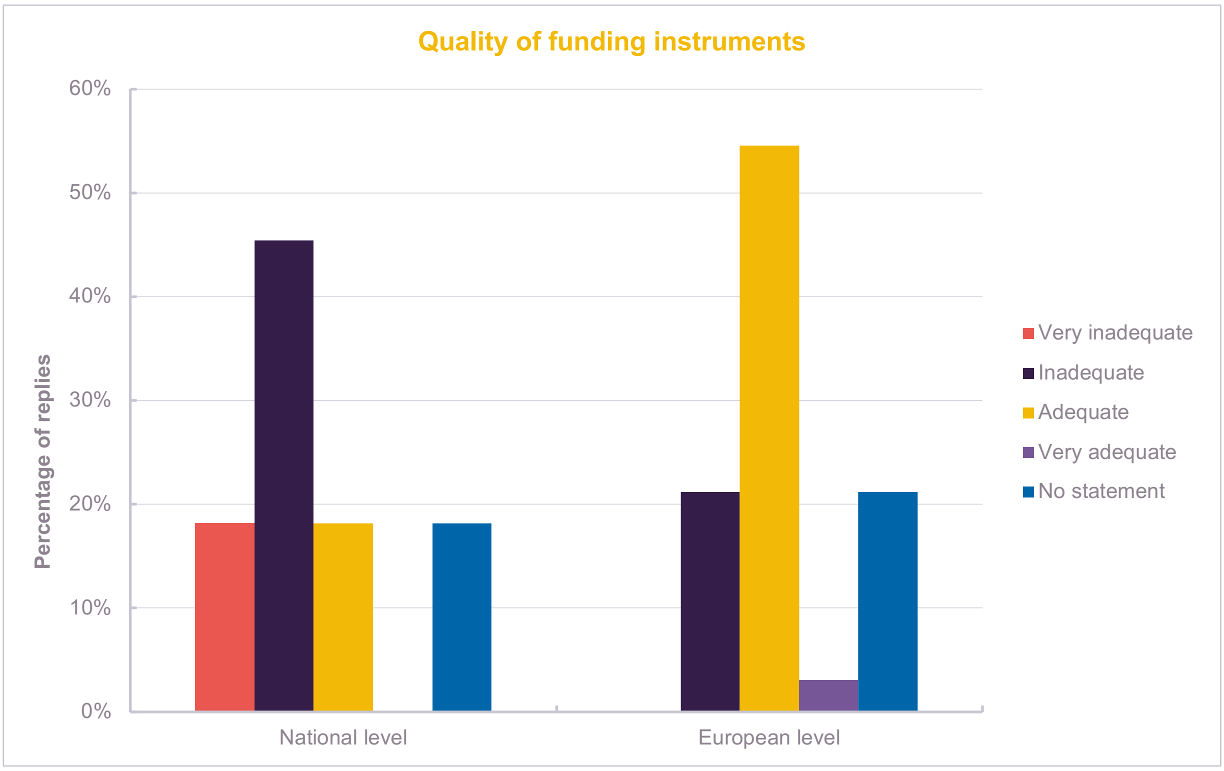


Figure 5.4 Appropriateness of the available funding instruments related to human factors in transport safety.

5.2.10. Do you think that the current regulations and directives at European level are adequate for the development (design and testing) of vehicles with increasing levels of automation?

Since national regulations on trial approvals differ a lot between countries, in the survey only three regulations on EU level were considered:

- Commission recommendation 2008/653/EC on safe and efficient in-vehicle information and communication systems
- Regulation (EU) 2019/2144 (General Safety Regulation)
- Commission implementing Regulation (EU) 2022/1426 type approval of ADS of fully automated vehicles.

Responses were analysed according to the participant's expertise (see Figure 5.5):

- 42% of experts on HMI and Human Factors stated that the Commission recommendation 2008/653/EC is not sufficiently adequate.
- 46% of experts on driver state stated that the Regulation (EU) 2019/2144 is moderately adequate.
- 44% of experts on vehicle automation and validation tests (with simulator and o-road) stated that the Regulation (EU) 2022/1426 is moderately adequate.

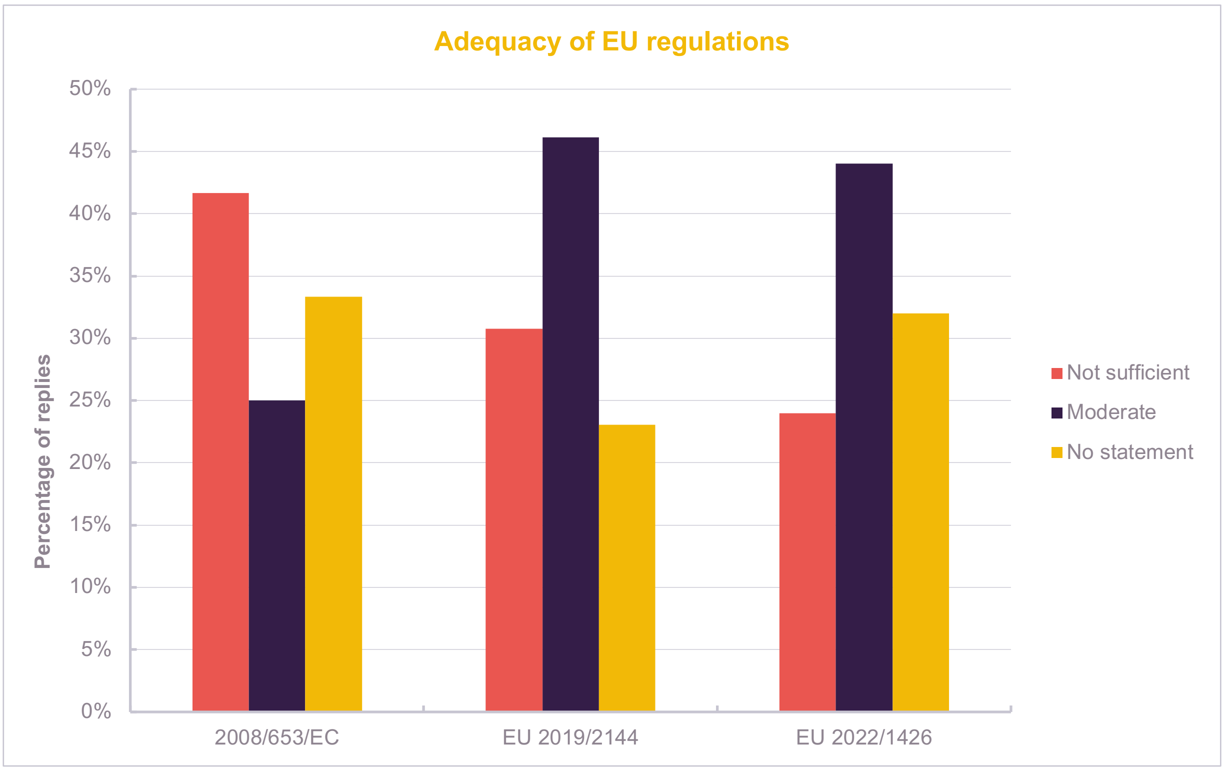


Figure 5.5 Adequacy of EU regulations for the development (design and testing) of vehicles with increasing levels of automation.

5.2.11. Do the current regulations and directives at European level contribute to the development (design and testing) of vehicles with increasing levels of automation in a negative or positive way?

Responses were analysed according to the participant's expertise (see Figure 5.6):

- 42% of experts on HMI and Human Factors stated that the Commission recommendation 2008/653/EC contributes negatively.
- 31% of experts on driver state stated that the contribution of the Regulation (EU) 2019/2144 is positive.
- 40% of experts on vehicle automation and validation tests stated that the Regulation (EU) 2022/1426 contributes positively.

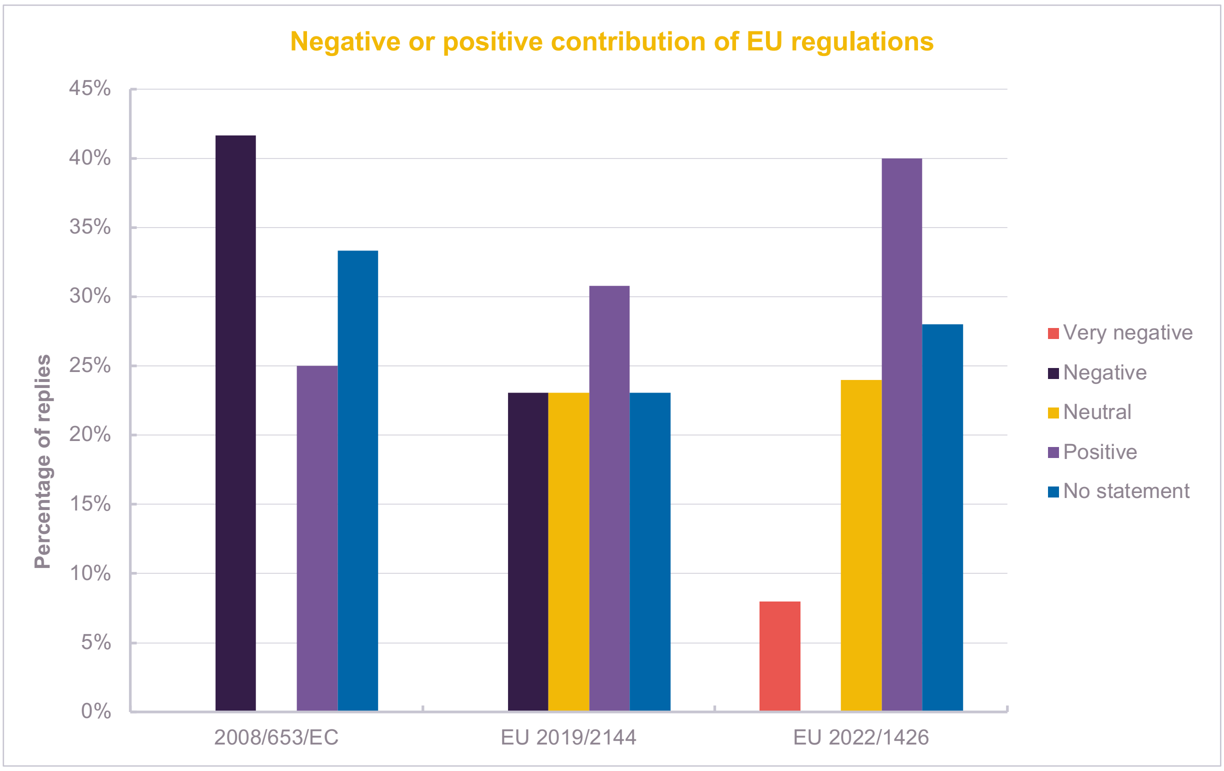


Figure 5.6 Negative or positive contribution of EU regulations to the development (design and testing) of vehicles with increasing levels of automation.

5.2.12. Recommendations

The participants were asked to express recommendations for working within the framework of existing laws and regulations.

Due to the varied sample of experts involved, some recommendations that were received are strictly linked to issues that the consortium partners encountered during the project tasks, others highlighted issues that were not part of the MEDIATOR development (for example, under driver state detection many recommendations talked about the need to respond to situations of driver distraction - including mind wandering) or related to broader issues for automation in vehicles (i.e., responsibility, liability, insurance, ethics, etc..). The issues not encountered are included in exploitation roadmap for road transport (Fiorentino et al., 2023).

Recommendations are listed with reference to regulatory aspects, in the following fields:

- Driver state detection systems
- HMI design and Human Factors
- Vehicle automation (design and software)
- Validation tests (simulators and on-road)

5.2.12.1. Driver state detection systems

Regulation (EU) 2019/2144 General Safety Regulation updates EU type approval requirements to ensure the general safety of vehicles and the protection of vulnerable road users, is the regulatory reference for Driver state detection system.

The main answers, as reported by the participants, are listed as follows:

- There is not a standardised approach to refer to once the driver state, during driving, is detected. Some driver state detection systems are already equipped on existing vehicles, but it is not clear how they work, what kind of monitoring approach and accuracy they have.
- It is recommended to increase the medical content of each driver state detection system under development, in order to clearly define which kind of medical approach and knowledge (i.e., knowledge on physiological body states that can be measured by various sensors) have been considered into such developments. Everyone should consider the medical knowledge already available and the research trend in terms of human state analysis when developing driver state detection systems; the medical knowledge should drive all developments, in order to assure that every single driver state detection system that is equipped on a vehicle, will be compliant with the latest medical knowledge in terms of state analysis. Aligning the medical research in the field of human state analysis with the development of driver state detection systems will not only allow to develop reliable systems, but also to test and validate them on the basis of a clear state of art and, even more important, to update/upgrade them easily on the basis of further medical findings.
- Consider all physical factors and medical parameters that may be involved in the analysis (so, for example, do not consider only an assessment of fatigue status via Karolinska Sleepiness Scale assessment...).
- Driver monitoring should go from detection to prediction, also investigating a multi-factorial approach, i.e. it should for instance not only estimate the current level of driver fatigue but also predict (forecast) how the fatigue will likely develop (perhaps become worse) over the next 1 or 2 hours, in order to make more useful recommendations to the driver (e.g. to take a break), and to give more meaningful input to a Mediator-like system, allowing it to plan proactively with respect to that predicted degraded driver state (similar to the proactive planning possible based on predicted degraded automation state).
- Driver state detection systems shall not be invasive to the driver and should be designed according to a holistic approach.
- The lack of defined objective drowsiness measures presents some additional challenges to the development of driver monitoring systems and it is important that the validation protocols should discourage the implementation of pure warning systems to the driver, but promote the integration with automated systems, making them more sensitive when a driver is distracted.
- Identify level of drowsiness and risk of sleep stroke occurring on drivers of dual mode vehicles and analyse the condition of the occupants of autonomous vehicles to anticipate possible risks brought by sudden illnesses (e.g., heart attack) or out-of-norm physical-psychological conditions (e.g., panic attacks) of passengers, which may create safety problems.
- Use sensors fusion for monitoring drowsiness (more than one source of data).
- Driver Cognitive distraction (mind wandering) estimation should be more deeply investigated.
- Include instrumented steering wheel in R&D tests at level L3 to monitor driver intentions and reactions.
- A driver can have different reaction speeds, depending upon her/his level of attention when the context requires that she/he takes over the autonomous driving system. The ability to properly identify these levels of attention could make the driving more comfortable and safer.
- Modify privacy regulations to better calibrate algorithms and sensors.
- Enlarge the driver's physical condition monitoring before driving (for example an alcohol test that blocks the engine from starting if it is positive).
- Do not just look at the driver state but do that in relation to the state of the vehicle to drive under the same conditions.
- Evaluate and introduce recovery actions in case of late reaction from the driver to the system.
- Enable self-driving vehicles to monitor the state of vehicle occupants to deploy the correct action depending on the situations and on the traffic scenario.

* Driver Monitoring should include emotions, because emotions can strongly affect the capacity to properly react to a take-over request.
* It is recommended to have investigate emotional aspects further as it is relevant for user's acceptance of AD.

5.2.12.2. HMI design and Human Factors

Commission recommendation 2008/653/EC is the regulatory reference for HMI design and Human Factors.

The main answers, as reported by the participants, are listed as follows:

* Customise HMI design according to automotive OEMs and customer needs.
* HMI customisation could be relevant for brand acceptance, but a standard guideline could allow the driver to avoid possible misunderstandings.
* Encourage a standard approach to HMI design.
* HMI customised according to user preferences.
* Make HMI easy to understand and to use.
* HMI countdown properly calibrated on vehicle speed.
* Define appropriate and measurable parameters to be able to quantify trust and acceptance.
* Undertake human factors studies for L4 vehicle acceptability for people inside and outside the vehicle.

5.2.12.3. Vehicle automation (design and software)

Regulation (EU) 2022/1426 for the type-approval of ADS of fully automated vehicles, is the regulatory reference Vehicle automation (design and software).

The main answers, as reported by the participants, are listed as follows:

* The road/vehicle authorities should specify the Operational Design Domains (ODDs) in which a certain vehicle needs to operate (e.g., all highways in the Netherlands including entrances and exits under all local weather and lighting conditions that can be reasonably expected). Vehicles are allowed to drive in automation mode only in ODDs that match those allowed by the road/vehicle authorities and those declared as feasible in automation mode by the OEMs for the specific vehicle. At the same time this may be difficult, as different OEMs may have vehicles capable of different (more extensive or narrower) ODDs.
* Harmonise the ODD for AD systems.
* ODD should consider mixed traffic and complex scenarios.
* It is recommended to keep the driver in the loop, especially when the levels of automation are L3 and L4 and the driver needs to take over manual driving either at L3 (when requested by the automated system) or in L4 at the end of the ODD.
* Trust with users on vehicle automation is still an open point. It is recommended to implement human-like vehicle automation interactions with the users to maximise users' trust.
* It is recommended that unharmonised rules to apply to test and drive vehicles in automation mode do not affect the design of vehicle automated functions on a country-by-country basis otherwise this may jeopardize vehicle automation performances when driving from one country to another.
* When defining regulations for driving in automation mode, it is recommended to start from the best practice and lesson learnt from the regulations in place for vehicle functions/services, increasing real time data as well as the complexity and the number of scenarios.

5.2.12.4. Validation test (simulator and on-road)

Regulation (EU) 2022/1426 for the type-approval of ADS of fully automated vehicles, is the regulatory reference for Validation test (simulator and on-road).

Complexity of testing on real road systems like Mediator, due to transferring control to the human user, mitigation of degraded driver fitness and automation take-over proposal when it is judged capable of doing so, highlighted the necessity to forecast validation tests with driving simulator to reduce the variability of test in real environment.

For report readability, the main answers, as reported by the participants, were divided and listed in global recommendations for validation, recommendations for tests with driving simulators and recommendations for on-road tests.

Global recommendations

- Clearly define responsibility roles (carmaker, supplier, driver, etc.…).
- Manage the different level of ages and competences of the drivers (i.e., the different ability to read info on display due to glasses or eyes defects).
- Increase number of tests and validations with different types of users to consider the huge amount of false positives vs the alert messages.
- Large and inclusive validation campaigns including different people, countries, driving context, etc, are needed, as database for offline testing too.
- Set-up a central database with multiple scenarios/use cases to be used to validate the solution.

Tests with driving simulators

- Undertake strength and streamline validation tests with simulator to specialize testing scenarios and related algorithms.
- Develop a common methodology for carrying out the tests, also to be able to compare the results obtained by different organisations.
- Define criteria to classify standard driving simulators. Classification is necessary because it is crucial to determine the appropriate type of simulator to employ for the desired purpose or to compare simulator capabilities and options.
- Introduce simulator tests as mandatory for a realistic and feasible validation phase of AD systems.
- Promote driver training with driving simulators to gain sufficient confidence with the in-vehicle autonomous systems.
- A roadblock to vehicle automation is a still very low understanding of the interaction of human driving on automated vehicle dynamics (when taking over the driving task) and on human comfort when in automation mode. The recommendation is to perform specific tests on dynamic driving simulators.

On-road tests

- Naturalistic driving studies should be encouraged.
- Regulations should be more flexible towards on-road testing.
- Introduce general testing policy towards on-road permission and conditions. Today it is very complicated to organise and manage on-road tests in terms of legal compliance.
- Define a common European protocol for testing AD, especially in terms of permissions and regulations.
- It is difficult to perform reliable and effective on-road testing, due to several legislation restrictions which aim to guarantee the safety level of such activities. The recommendation is

to involve the medical field during on-road testing, in order to be in the position to monitor in real time, even if remotely, the progress of the driver status during the on-road testing.

- It is recommended a common validation methodology, building on the outcomes of European projects like L3Pilot (l3pilot.eu) and Hi-Drive (www.hi-drive.eu), is adopted at European level by all Member States in conjunction with harmonised rules to apply for permission to test and drive in automation mode.
- Undertake a large-scale vehicle automation field operational test at EU level.
- Today each EU Member State has very diverse rules for getting permission to drive vehicles in automation mode. It is highly recommended to harmonise the corresponding rules in the whole of Europe.
- Autonomous driving needs a large validation on-road because there are relevant differences among the various countries (road type, signs, ...). Often different countries have different regulations to drive prototypes and this does not help.
- Coupling between simulation tests and on-road tests for better coverage of large sample of scenarios in mixed traffic.
- Improve the Verification and Validation process; create a digital twin to model realistic behaviour of an ADS and to detect and fix issues before testing on-road, increase simulation tests, with the right level of safety and cybersecurity, and HIL test automation. This could reduce the number of on-road tests.
- It is recommended that the highest possible number of scenarios and use cases are taken within the vehicle automation design phase. To this goal it is highly recommended that a scenario database, including the highest possible number of the so called “edge cases”, is developed and applied at European level.

5.2.13. Recommended order of priority for adapting regulations amongst the different cross-cutting areas

The participants suggested the following priorities (see also Figure 5.7):

1. HMI design and Human factors
2. Driver state detection system
3. Vehicle automation design and Validation with on-road tests
4. AD software development
5. Validation test with simulators

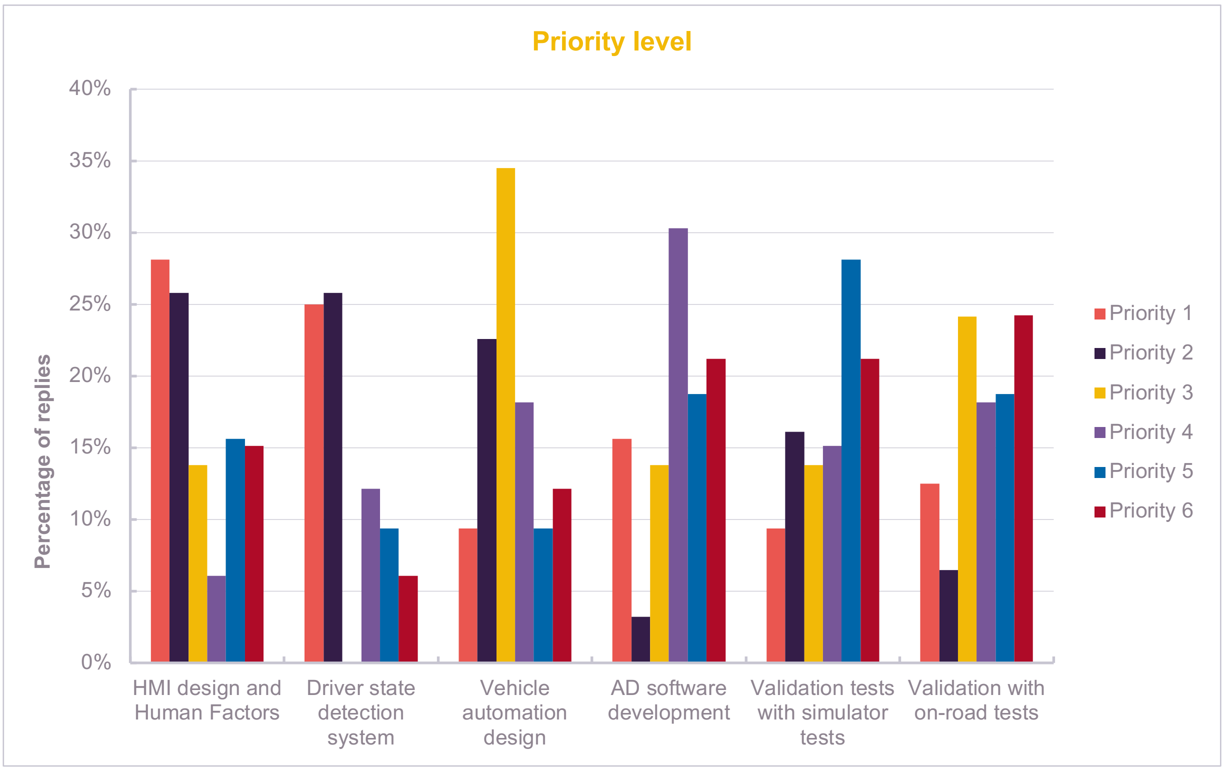


Figure 5.7 Recommended priority levels.

Replies reflect the main regulatory needs according to the actual development of systems like Mediator.

6. Recommendations

This chapter contains practical suggestions for improving future directives and regulations in the field of Mediator-like systems design at European level.

The recommendations were based on a questionnaire survey of all MEDIATOR participants (Chapter 4) and a web survey of external experts (Chapter 5) about possible recommendations for testing systems like Mediator within the existing legal and regulatory framework in Europe for potential policy changes that could improve the current regulatory framework.

Some recommendations received are strictly linked to issues encountered during the project tasks, others highlighted issues not encountered during the MEDIATOR development. The issues not encountered are included in Fiorentino et al. (2023).

A total of 18 recommendations have been made and can be divided in four groups:

- Driver state detection systems
- HMI design
- Vehicle automation
- Validation tests.

6.1. Recommendations on Driver State detection systems

Regulation (EU) 2019/2144 General Safety Regulation updates EU type approval requirements to ensure the general safety of vehicles and the protection of vulnerable road users.
The regulation recognises the driver state detection system (driver drowsiness and attention warning) as a safety system that has the potential to reduce casualty numbers. This system will form the basis of technologies which will also be used for the deployment of automated vehicles.

Complementary recommendations in addition to Regulation (EU) 2019/2144 are labelled and numbered with the acronym DSRX meaning Driver State Recommendation number X.

6.1.1. DSR1: Standardise the features of DMS

6.1.1.1. Justification

Different manufacturers have different solutions, and it is difficult for a user to know what the driver monitoring system is capable of. Some systems detect sleep, others drowsiness or distraction, and yet others detect non-responsiveness. This is done by different sensors and different techniques, such as cameras, driving time and variability in lane position. This has safety implications since the users do not know what to expect from a certain system in terms of functionality, accuracy, and timing. This will become more important as vehicles are equipped with more advanced automated functions, since users are likely to exploit the driver monitoring system to maximize non-driving related tasks (continue texting until the vehicle tells driver that he/she is inattentive, continue to face the passenger during a conversation until the vehicles tells the driver to look back at the road, etc.).

6.1.1.2. Explanation

The functionality and output of driver monitoring systems should be harmonised to increase user understanding and acceptance. Furthermore, the current regulations lack a rationalization for driver state detection system. Some driver state detection systems are already equipped on existing vehicles, but it is not completely clear how they perform (e.g., only distraction, fatigue, etc.), which kind of monitoring approach they have and which kind of accuracy they bring to the driver. It is recommended to standardise the functionalities and output from DMS to increase user understanding and acceptance.

6.1.2. DSR2: Harmonise validation criteria for driver monitoring systems

6.1.2.1. Justification

Driver monitoring systems are becoming more complex, with multiple sensors, multiple features, and multiple applications. Driver monitoring systems that have been evaluated against a standardised set of requirements will be more transparent for users (relating also to DSR1) and will also set a minimum functionality/accuracy level for driver monitoring systems.

6.1.2.2. Explanation

Testing and validation of such integrated complex systems would benefit from a modular design approach, with clear specifications of functional requirements with layers, of interfaces between layers, and of validation criteria for each layer (François, & Wertz, 2021). Separate layers can be foreseen for sensors, image/signal processing, feature extraction/analysis, and application/countermeasures. The advantage of the modular approach is that changes can be made to individual layers without having to redo the validation process for the entire driver monitoring system chain.

The recommendation to harmonise validation criteria for driver monitoring systems should be based on state-of-the-art human state knowledge and reproducible and objective data. Validation criteria should also require a minimum level of accuracy, sensitivity and specificity that is high enough to provide transparent, meaningful, and acceptable results (meaningful detections with few false warnings).

6.1.3. DSR3: Increase the medical content of each driver state detection system under development

6.1.3.1. Justification

Insights coming from biomedical research and the integration of knowledge of human physiology could have an impact on the development of reliable systems.

The development of driver state detection systems uses different terminology, definitions and experimental approaches in comparison to the medical field. Identifying the level of drowsiness, as well as the risk of falling asleep, could anticipate possible risks brought by sudden illnesses or out-of-norm physical-psychological conditions (e.g., panic attacks...) of passengers, which may create safety problems.

6.1.3.2. Explanation

The recommendation to increase the medical content of each driver state detection system under development, could allow the current system for detection of sleepiness and fatigue levels the integration of devices capable to identify the occurrence of diseases or subclinical conditions that can interfere with driving capabilities or promote drowsiness.

6.1.4. DSR4: Promote the integration of more sensitive warning systems

6.1.4.1. Justification

The lack of defined objective drowsiness measures presents challenges to the development of driver monitoring systems. DMS should not only detect driver impairment, but also predict future impairments, and DMS-based countermeasures should adapt active safety systems, in addition to warnings.

6.1.4.2. Explanation

The integration of devices capable to identify the occurrence of diseases or subclinical conditions could enhance current systems for detection of sleepiness and fatigue levels.
The recommendation to promote the integration of more sensitive warning systems, including a driver's physical condition control system able to act before it is too late and not just when the driver is almost nonresponsive, could improve the driver state detection system.

6.1.5. DSR5: Use synthetic data for calibration of driver state camera based systems

6.1.5.1. Justification

Drivers react to an event with different speed and in different ways, especially when he/she is asleep and/or distracted. To calibrate the driver state camera based system a large and massive data collection is required, also with sleep deprived participants. According to the GDPR, tests and data collection involving volunteers (within the on-road or driving simulator studies) had to guarantee that requirements related to participants' mental and physical safety, their privacy, and data protection were met.

6.1.5.2. Explanation

The recommendation to use synthetic data for calibration of driver state camera based systems will allow to reduce the on-road validation tests and to be compliant with the GDPR. Furthermore, training the AI models will allow data scientists to unlock advantages such as:

- Improved data quality – real-world data is often full of errors, containing inaccuracies or representing a bias that may affect the quality of a neural network. Synthetic data ensures higher data quality, balance, and variety. Artificially generated data can automatically fill in missing values and apply labels, enabling more accurate predictions
- Scalability – machine learning requires massive amounts of data. It is often difficult to obtain relevant data on the necessary scale for training and testing a predictive model. Synthetic data helps fill in the gaps, supplementing real-world data to achieve a larger scale of inputs
- Ease of use – synthetic data is often simpler to generate and use. When collecting real-world data, it is often necessary to ensure privacy, filter out errors, or convert data from disparate formats. Synthetic data eliminates inaccuracies, duplicates, and ensures all data has a uniform format and labelling.

6.1.6. DSR6: Enhance the validation approach with multi-laboratory trials

6.1.6.1. Justification

Lack of standardized test methods and test scenarios have led to a subjective interpretation of “efficacy”, particularly for Driver Monitoring Systems. Actual standards provide some guidelines for testing methods and approaches for a product development cycle, but they are not completely able to deal with the complexities of DMSs.

6.1.6.2. Explanation

The recommendation to enhance the validation approach should promote multi-laboratory trials. To allow these tests to be more broadly used by the regulatory bodies, orchestrated efforts are required to show the robustness and reliability of those methods, which can accelerate the use for early testing.

6.1.7. DSR7: Specialise the driver state validation tests

6.1.7.1. Justification

Drivers can have different reaction speeds depending upon their level of attention when the context requires them to take over from the autonomous driving system. The ability to properly identify these levels of attention could make the driving more comfortable and safer. During the drive, a continuous monitoring could determine the driver status and decide if the car should stop or continue autonomously if it can.

6.1.7.2. Explanation

The recommendation to specialise the driver state validation tests should be based on two main steps: preliminary validation and on-road test.

- Preliminary validation. Simulation data could help in the preliminary assessment of driver state in compliance with GDPR, as well as reducing the number of real on-road validation tests.
- On-road test. Today are available prototypes with instrumented steering wheel for driver actions monitoring. These systems are capable to monitor driver intentions and reactions (L3). Encouraging the set-up of shared database, including different people, countries, driving context, etc…, could help to have offline test and to improve such a kind of system.

6.1.8. DSR8: Adapt active safety systems based on driver state detection information

6.1.8.1. Justification

Active safety systems targeting critical manoeuvres can be adapted based on information from the driver monitoring system. For example, an autonomous emergency brake intervention could be delayed in situations where the driver is attentive to the forward roadway. This would reduce the number of false interventions in overtaking situations. Similarly, interventions could be initiated earlier in situations where the driver is inattentive, for example if the driver is looking elsewhere while approaching a pedestrian.

6.1.8.2. Explanation

Adapting active safety systems based on driver state detection information could help mitigate risks of critical situations as well as avoid unnecessary interventions if they are coupled with the vehicles safety functions.

6.2. Recommendations related to HMI design

Commission recommendation 2008/653/EC summarises the essential safe design and use aspects to be considered for the human-machine interface (HMI) for in-vehicle information and communication systems. The recommendation promotes the introduction of well-designed systems into the market, and by considering both the potential benefits and associated risks, they do not prevent innovation within the industry. It contains principles, which may be reinforced by national legislation or by individual companies, constituting the minimum set of requirements to be applied.

Complementary recommendations in addition to Commission recommendation 2008/653/EC are labelled and numbered with the acronym HMIRX meaning HMI Recommendation number X.

6.2.1. HMIR1: HMI Standards

6.2.1.1. Justification

In the automotive domain and when dealing with automated vehicles too, it will be important to take care of HMI standardisation topic to allow the creation of a common dictionary and the development of HMI systems both inside the vehicle (for the user/driver) and outside the vehicle (for the other road users, e.g., pedestrians, motorcyclists, vehicles automated and not automated) accepted worldwide.

6.2.1.2. Explanation

Standard HMI could be helpful in avoiding the user gets confused in the transitions between assisted driving and automated driving and vice versa and also when the automated vehicle has control.
The recommendation to work on internal and external HMI standards for automated vehicle at international level, could have positive effects:

- The international standardisation activities at ISO level on automated vehicles topics (e.g., taxonomy and definition of terms, external HMI ergonomic guidelines,…) could create a robust base for the design guidance of the OEMs, which will then customise their brands, being sure the fundamental aspects will be respected.
- The colour aspects, which can be an important parameter for brand customisation and users' personalisation should ~~be considered in a standardisation approach to~~ take care of usability, safety and inclusivity issues

6.2.2. HMIR2: Customisation of HMI systems

6.2.2.1. Justification

The HMI has a paramount importance in improving the user experience while using automated vehicle. The personalisation aspects of the HMI can be crucial in enhancing this user experience. The personalisation can be designed at different levels, from the driving style of the automated vehicle to the internal comfort parameter (light, temperature...), up to the HMI appearance (colours, graphics...) to cope with environment and users' requirements.

6.2.2.2. Explanation

Through the User-Centred Design process, using different kind of fidelity levels HMI prototypes (e.g., paper & pencil, PC prototype, real prototype), testing scenarios (e.g., usability laboratory, driving simulator, track, real road) and evaluation methods (ethnographic research, heuristics analysis, user testing...), it will be possible to study the personalisation of the interaction between users and the automated vehicle HMI.
The recommendation to allow an HMI design customisation according to user preferences could have positive outcomes on preventing and minimizing motion sickness, on creating a higher internal cabin comfort, on understanding the vehicle mode without leading to doubts related to the status of the car, on increasing the taking care of the specific preferences and needs. This approach to personalisation will enhance the acceptance of the automated vehicle experience, beyond its safety.

6.2.3. HMIR3: Anticipate users' acceptance tests for HMI using WoOz approach

6.2.3.1. Justification

HMI in automated vehicles (AVs) is a crucial aspect to allow for users' acceptance of this important innovation. To design automated vehicles with a high users' acceptance, it is indispensable that their HMI has a high usability. Tests with users are generally planned at the end of the vehicle development when the vehicle is almost completed and when all HMI features have been implemented.

6.2.3.2. Explanation

To cope with one of the User-Centred Design process principles, different kinds of naïve users (young, elderly...) with different abilities (visual, cognitive characteristics...) should be involved throughout the HMI design and development, since the very beginning. A WoOz technique allows users to interact with a system that they believe real, but which is controlled, completely or partially, by a human being, the wizard (Kelley, 1984), who can be hidden.
The recommendation to anticipate the user's tests on automated vehicle HMI using a WoOz approach could allow to evaluate the usability and acceptance of HMI with users' samples, even if the AV is not yet fully developed.

6.3. Recommendations related to Vehicle Automation

Regulation (EU) 2022/1426 for the type-approval of ADS of fully automated vehicles furnishes the administrative provisions and technical specifications for the type-approval of automated driving systems of fully automated vehicles. Moreover, the Regulation aims to significantly reduce deaths and serious injuries on European Union (EU) roads by introducing state-of-the-art safety technologies as standard vehicle equipment, and to enhance the competitiveness of EU car manufacturers on the global market by providing the first ever EU legal framework for automated and fully automated vehicles.

Complementary recommendations in addition to Regulation (EU) 2022/1426, are labelled and numbered with the acronym VARX meaning Vehicle Automation Recommendation number X.

6.3.1. VAR1: Test automated vehicles (AVs) in interaction with other traffic participants

6.3.1.1. Justification

Today's legislation focuses very much on "traditional" values and technologies. The focus is on the driver/operator of a vehicle because currently only humans can be hold responsible, especially when a third party is damaged. Therefore, it is usually assumed that there is always a driver/operator placed in the vehicle and that the driver/operator is able to control the vehicle (or is able to overrule automated functions).
In the next years there will be a progressive increase in the number of AVs on public roads. However, there will never be only AVs, but rather mixed traffic environments due to the presence of other traffic participants (including human driven cars).

6.3.1.2. Explanation

The development of automated vehicle systems fosters the need for testing such transport systems in such environments on public roads. The intention behind such tests is to learn which requirements (on owner, driver, operator, vehicle and/or infrastructure) must be defined in future legislation with regards to AV systems so that they can become a "standardised" and integrated part of the traffic/transport systems of our societies.

Policy makers shall consider a mixed traffic modality, in which automated vehicles will share traffic with other traffic participants (non-automated cars, pedestrians, cyclists, etc.). For this reason, it is recommended to test AVs in interaction with other traffic participants for validation of mixed traffic and complex scenarios.

6.3.2. VAR2: Improve Operational Design Domains

6.3.2.1. Justification

Vehicle authorities specify the Operational Design Domains (ODDs) in which a certain vehicle needs to operate. For example, all highways including entrances and exits under all weather and lighting conditions that can be reasonably expected. Vehicles are allowed to drive in automation mode only in ODDs that match those allowed by the road/vehicle authorities and those declared as feasible in automation mode by the OEMs for the specific vehicle.

Vehicles provided with automated driving systems are envisioned to be the sustainable future for enhanced road safety, efficient traffic flow and decreased fuel consumption, while improving mobility. AI offers the potential to transform our lives in radical ways, particularly when it is combined with the rapid development of mobile communication and advanced sensors, thus allowing autonomous driving to make great progress. In fact, AVs can mitigate some shortcomings of manual driving: reduction in human-caused accidents and the realisation of a more efficient driving task in terms of energy consumption, traffic flow and driver's workload. However, the underlying technology is not yet mature enough to be widely applied in all scenarios and for all types of vehicles, due to complex transportation environments, imperfect road infrastructure and even legal issues.

6.3.2.2. Explanation

The recommendation to improve ODDs should cover the ODDs definition, ODDs use, and ODDs application and how they integrate into standards and AV development.

For this, an intelligent decision-making system could be designed and integrated to provide the optimal decision on which is the best action to perform, by using an explainable and safe paradigm, based on several techniques (i.e., probabilistic). To take appropriate/suitable decisions for a given ODD it is limited by sensing the ODD (which can be affected by sensor limitations) and take an appropriate decision (based on surroundings and the vehicles driving automation system capabilities. For example, in heavy precipitation and bad lane markings most systems cannot perform nowadays). To improve the working of vehicle driving automation systems, the system must be capable of sensing an environment properly and also have a good sense of what it is capable of and over time extend the ODDs. Verification and validation are integral parts of that process.

6.3.3. VAR3: Privacy – Preserving AI (PPAI)

6.3.3.1. Justification

Federated Learning promotes knowledge acquisition by aggregating the results of multiple participants without the need to store the individual data points, avoiding private data leaks. At the level of drivers, this is known as cross-device since it relies on the participation of individuals. The same approach is also possible if we generalise the concept under the automotive companies' perspective. In this case, Federated Learning becomes cross-silo, as it no longer relies on individuals but on silos of data.

Complementing Federated Learning, Trusted Execution Environments (another PPAI technology) can further enhance data security by avoiding access to participants' data, even for privileged cloud administrators.

6.3.3.2. Explanation

The recommendation to use PPAI and Federated Learning especially for knowledge acquisition could apply to the automotive industry. As privacy is at the basis of Federated Learning, there would be less resistance with participants to engage. In addition, as each driver would have a copy of the final model, the response time could be significantly lower, allowing fast inference for safety applications.

6.4. Recommendations related to Validation Tests

Regulation (EU) 2022/1426 for the type-approval of ADS of fully automated vehicles.

Complementary recommendations with respect to validation tests in addition to Regulation (EU) 2022/1426, are labelled and numbered with the acronym VTRX meaning Validation Tests Recommendation number X.

6.4.1. VTR1: Verification and Validation activity also by digital twins

6.4.1.1. Justification

Prior to on-road automated vehicle tests, Verification and Validation methods are important for several reasons:

- Ensuring safety - Automated vehicles are complex systems that must operate safely in a variety of real world situations. Verification and Validation methods help to ensure that the vehicles are safe and reliable by identifying potential issues and addressing them before they are tested on-road.
- Reducing costs - Verification and Validation methods can help to identify problems early in the development process when they are less expensive and time-consuming to fix. This can reduce the overall cost of the project and ensure that it stays within budget.
- Satisfying regulatory requirements - Automated vehicles are subject to strict regulatory requirements, and Verification and Validation methods are often required as part of the regulatory approval process. Using these methods prior to on-road testing can help to ensure that the vehicles meet these requirements and are approved for operation.

Building stakeholder confidence - The public and other stakeholders expect automated vehicles to be safe and reliable. Using Verification and Validation methods prior to on-road testing can help to build confidence in the system and increase public acceptance of these vehicles.

6.4.1.2. Explanation

The Verification and Validation process should be thorough and systematic, to ensure that the system operates safely and effectively, and meets the expectations of both regulators and users. The Verification and Validation process could help to detect and fix critical issues and then, to confirm that an ADS meets its specified requirements and operates safely and effectively under a range of real world conditions.
To complete the verification and validation assessment the recommendation is to include digital twins to validate reliably the performance of the system in a wide range of scenarios, without the need for physical testing on the road.

6.4.2. VTR2: Increase use of simulators

6.4.2.1. Justification

On-road testing should be coupled with virtual simulation-based or driving simulator-based testing approaches to improve the reliability and the coverage of the test itself.

6.4.2.2. Explanation

Combining on-road vehicle tests with simulation tests and driving simulator tests can offer several advantages for vehicle manufacturers, researchers, and regulators:

- Cost savings - On-road testing can be expensive and time-consuming, especially when testing a large number of vehicles or conducting tests under different driving conditions. Simulation testing allows researchers to test a vehicle's performance in a variety of scenarios at a fraction of the cost.
- Controlled conditions - Simulation testing allows for the creation of controlled conditions that may be difficult or impossible to replicate in real world driving, such as extreme weather or rare accident scenarios. This can provide researchers with more accurate and reliable data.
- Safety - Simulation testing provides a safe and controlled environment for testing new technologies, such as autonomous vehicles, without the risk of endangering human drivers or pedestrians.
- Flexibility - Simulation testing allows researchers to modify and test various components of a vehicle, such as its engine, brakes, or suspension, without the need for physical modifications or prototypes.
- Data analysis - Simulation testing provides researchers with more detailed data and analytics that can help identify potential issues or areas for improvement.

6.4.3. VTR3: New harmonised European regulation

6.4.3.1. Justification

It is currently hard to perform reliable and effective on-road testing now due to several legal restrictions which aim to guarantee the safety level of such activities. Moreover, each EU Member State has its own specific regulation in terms of permission and conditions for on-road test with AVs (see as an example what is required in Sweden - Section 3.3.1 - and Italy - Section 3.3.2).

6.4.3.2. Explanation

The recommendation to have a new harmonised European regulation for on-road testing of automated vehicles could have the following benefits:

- Safety - Automated vehicles are a new technology, and there is still a lot of work to be done to ensure their safety. On-road testing is crucial for identifying potential safety issues and risks that may not have been identified during simulation or laboratory testing.
- Harmonisation - A common European regulation would ensure that all Member States are testing automated vehicles under the same set of rules and standards. This would prevent the creation of a patchwork of regulations, which could be confusing for manufacturers and inhibit the development and deployment of automated vehicles. Indeed, this may jeopardize vehicle automation performances when driving from one country to another.
- Innovation - A common European regulation would encourage innovation in the development of automated vehicles. It would provide a clear framework for manufacturers to test their vehicles and ensure that they meet safety and performance standards, which would in turn increase consumer confidence in the technology.
- International competitiveness - A common European regulation would help to ensure that Europe remains competitive in the global market for automated vehicles. By creating a clear framework for testing and development, Europe would be able to attract investment from manufacturers and maintain its position as a leader in the field.

6.4.4. VTR4: Large-Scale Vehicle Testing

6.4.4.1. Justification

Large-scale on-road vehicle testing involves testing many vehicles on actual roads, highways, and other driving conditions. Large-scale on-road vehicle testing is essential because it allows automakers and regulators to gather data on how vehicles perform in real world conditions, rather than in controlled laboratory settings.

6.4.4.2. Explanation

To obtain feasible and significative on-road test validation results, a large-scale vehicle automation field operational test should be planned. This is required and necessary if one considers the current differences between countries in terms of regulations.

The large-scale vehicle testing should allow to evaluate the performance, reliability, and safety of new vehicle models or to gather data on existing vehicles in real-world conditions.

The recommendation for a large-scale vehicle testing could help to define a novel common (hence harmonised) regulation for automated driving tests. This can help identify potential safety risks or performance issues that may not be apparent during laboratory testing. It can also help to identify areas for improvement and guide the development of more efficient and environmentally friendly vehicles.

7. Conclusions

Automated transport technology is developing rapidly for all transport modes, with huge safety potential. The transition to full automation, however, brings new risks, such as mode confusion, overreliance, reduced situational awareness and misuse. The driving task changes to a more supervisory role, reducing the task load and potentially leading to degraded human performance. Similarly, the automated system may not (yet) function in all situations. Mediator optimises the safety potential of vehicle automation during the transition to full (level 5) automation. It will reduce risks, such as those caused by driver fatigue or inattention, or on the automation side, imperfect automated driving technology.

For automated mobility to gain societal acceptance only the highest safety and security standards will suffice. New risks such as overreliance on, and misuse of, technology should be addressed. Ethical issues are an equally important topic for automated mobility. Automated vehicles are required to be safe, respect human dignity and personal freedom of choice.

The EU is the first region in the world to combine vehicle approval rules with market surveillance rules (Regulation (EU) 2018/858). From this framework, the Commission started working on the development of a new approach for certifying the safety of automated vehicles which is less design specific and more adapted to the evolutionary nature of these vehicles. New and ground-breaking vehicle automation technologies can already be validated today under the EU vehicle approval framework (Regulation (EU) 2019/2144 and Regulation (EU) 2022/1426). Technologies not foreseen by EU rules can be approved through an EU exemption, granted based on a national ad-hoc safety assessment. The vehicle can then be placed on the EU market like any other EU approved vehicle.

This report provides recommendations for working within the framework of existing laws and regulations as well as for adjusting this framework to better reflect the changing functional and logical requirements for vehicle testing as levels of automation increase.

In detail, the report examines regulatory environment within Europe in which technology like Mediator is being developed. Only the regulatory and legal issues encountered in developing and testing technologies like Mediator during MEDIATOR project have been considered. The consortium partners are aware that there are other legal and regulatory issues to address to ensure that technology like Mediator is safe and functions as expected technically and by the user when in real use (i.e., recovery actions in case of system fault, responsibility, etc…). it is relevant to underline that technologies like MEDIATOR are being developed in a time when there is a great deal of activity but success in terms of a safe, useful technology has not been achieved; however these aspects are foreseen in the MEDIATOR exploitation roadmap for road transport (Fiorentino et al., 2023).

Recommendations were based on a questionnaire survey of all MEDIATOR participants and a web survey of external experts about possible recommendations for working within the existing legal and regulatory framework in Europe. Most of the lessons learned from the MEDIATOR participants describe issues relating to how the project team worked together especially relating to its multidisciplinary nature which needs establishment of a common language and concepts, as well as problems of projects that require integration of different components and that may be developing at different paces.

Recommendations are related to:

- Driver state detection systems
- HMI design
- Vehicle automation
- Validation tests.

These recommendations should help further exploitation of the potential safety benefits of the Mediator system and similar support systems.

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Mediator

Appendix A Ethical submission forms

A.1 Main form

Mediator ~ Ethical review board

Application for approval to use humans as subjects in empirical study

I. General

Name of Research Project:

To which agency is the proposal being submitted (or has been submitted):

Principal Investigator/s:

Name:	Name:
Company/organization/University:	Company/organization/University:
Academic Position (Other position):	Academic Position (Other position):
Office Telephone:	Office Telephone:
Mobile Phone:	Mobile Phone:
Organization email:	Organization email:
Other email:	Other email:

Name(s) of those conducting the research (if different from above):

Name:	Name:
Company/organization/University:	Company/organization/University:
Academic Position (Other position):	Academic Position (Other position):
Office Telephone:	Office Telephone:
Mobile Phone:	Mobile Phone:
Organization email:	Organization email:
Other email:	Other email:

Mediator ~ Ethical review board

Application for approval to use humans as subjects in empirical study

II. Consent to participate

1. Are the subjects able to legally consent to participate in the research? ☐ Yes/ ☐ No

   If you answered "No" to question 1, complete section IIb

2. Will the subjects be asked to sign a consent form?

   If you answered 'No' to question 2, explain here:

IIb. Subjects who cannot legally consent (minors, mentally incapacitated, etc.):

3. Will the subject's legal guardian be asked to sign a consent form? ☐ Yes / ☐ No

   If you answered 'No', to question 3, please explain here:

4. Will the subject be asked to give oral consent? ☐ Yes / ☐ No

5. Are the instructions appropriate to the subjects' level of understanding? ☐ Yes / ☐ No

Comments:

6. If informed consent forms will be signed, how will the informed consent forms be stored to ensure confidentiality?

III. Discomfort

7. Will the participants be subjected to physical discomfort? ☐ Yes / ☐ No

8. Will the participants be subjected to psychological discomfort? ☐ Yes / ☐ No

   If you answered 'Yes' to question 7 or 8, add here a detailed explanation of the circumstances:

IV. Deception

9. Does the research involve deceiving the subjects? ☐ Yes / ☐ No

10. Is the decision on the part of the subject to participate in the study based on deception? (For example, if they are informed of their participation only after the event.) ☐ Yes / ☐ No

    If you answered 'Yes' to question 9 or 10, add here a detailed explanation why deception is necessary:

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Application for approval to use humans as subjects in empirical study

V. Feedback to the Subject

Note: Although feedback to the subject is recommended for *all* studies, it is required for studies that involve discomfort or deception. Feedback entails providing the subject, upon completion of the experiment, explanation of the experiment and its aims.

11. Will the subjects be provided with post-experiment oral feedback? ☐Yes / ☐ No

12. Will the subjects be provided with post-experiment written feedback? ☐Yes / ☐ No

If you answered 'No' to both questions 11 and 12, explain here:

VI. Compensation for participation

13. Will the subjects receive compensation for participation? ☐Yes / ☐ No

    Detail here the type and amount of compensation:

If you answered 'No' to question 13, explain the basis for participation:

VII. Privacy

14. Will audio and/or visual recordings be made of the subjects? ☐Yes / ☐ No
    a. If yes, are they informed of this fact in the informed consent form? ☐Yes / ☐ No

15. Will the data collected (apart from the informed consent form) contain identifying details about the subjects? ☐Yes / ☐ No
    a. If the data contains identifying details, please answer here: (1) What steps will you take to ensure the confidentiality of the information? (2) How will the data be stored? (3) What will be done with identifying information or recordings of the subjects at the end of the research?

VIII. Withdrawal from the Study:

16. Will subjects be informed that they may withdraw from the study at any time? ☐Yes / ☐ No

17. Will the subjects' compensation for participation be affected if they withdraw from the study before its completion? ☐Yes / ☐ No
    a. If yes, are they informed of this fact in the informed consent form? ☐Yes / ☐ No

Mediator ~ Ethical review board

Application for approval to use humans as subjects in empirical study

IX. Research Equipment

18. Does the research entail the use of equipment other than standard equipment, such as computers, video recording equipment? ☐Yes / ☐ No

19. If yes, does the equipment being used meet safety standard for use with human subjects? ☐Yes / ☐ No

Please specify which standards (include documentation where appropriate):

Signatories

Name:	Name:
Position:	Position:
Date:	Date:
Signature:	Signature:

Mediator ~ Ethical review board

Application for approval to use humans as subjects in empirical study

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This section is to be filled out by a member of the Human Subjects Research Committee only

Decision of the Committee:

Note: The decision of this committee pertains only to ethical considerations involved in the conduct of the research.

Request Number:

Request Sub-Number:

Title of Research Project:

Principal Investigator/s:

Approval for research: ☐ Granted / ☐ Denied

Comments to the researcher in the event that application has been denied:

Signature of committee:

Name:

Date:

Signature:

Name:

Date:

Signature:

A.2 Consent Form

Date: _______________

Consent to participate

Name of Research Project: ....

Principal investigator(s): ....

Dear Participant,

Please read carefully the explanation of the study and the instructions and make sure you understand all parts of the research. In case you have questions please ask the experimenter. Then, please complete the following details and sign at the end of the document.

After reading the research description, I, undersigned

First Name:	Last Name:
ID:	

1. Hereby declare my willingness to participate in the experiment as detailed in the document describing the study
2. Hereby declare that the PI/Experimenter: _________________________________
   Explained to me that
   a. The study is about:
   b. That I am free to decide not to participate in the study and I am free to stop my participation at any time during the experiment.
   c. That my personal identity will be kept confidential by any of those who are involved in the study and that my personal details will not be published in any publication including scientific publications.

Health declaration

I, undersigned

1. Declare that I have no health issues and that I am not under any medical treatment.
2. Declare that I am not suffering from nausea, head hakes, dizziness or any other issue that can disturb my driving or my ability to operate a computer.
3. Declare that all parts of the experiment were explained in details and that all my questions regarding the experiments and its parts were answered.

This declaration is confidential and will not be transferred or used for any purpose other than this study.

I declare that I have read and understand all the above including the experimental description and approve my consent to participate in the study

Subject details:
Full name: ____________________ Date: __________________ Signature: ________________

Name of experimenter explaining the study:

Full name: ______________________ Date: __________________ Signature: ________________

A.3 Research protocol

Name of Research Project:

Research Protocol:

The research protocol should contain a full description of the project stages that pertain to the experimental method and all interaction with the human subjects. If the project contains a series of experiments, describe the variations; also include description of type and number of subjects and subject recruitment method. If this type of protocol is one commonly used and/or if a similar protocol and methods have been used and published in the literature, please add references indicating so. Please do not submit the complete project proposal that was submitted to the funding agency, the protocol should be maximum 2 pages long.

A.4 Information sheet

Description of the study

Topic of the study: ....
Principal investigator(s): ....

Dear Participant,

Please read carefully this information sheet about the experiment. In case you have any questions, we would be happy to answer. Please make sure you fully understand the experiment and what you are asked to do. After reading this information sheet please read and sign the consent form.

Information about the study
In this study you will be asked to...

At the end of the study all forms and other information will be delivered to the principal investigator and will be kept under his/her sole responsibility.

Compensation
Participation in the study is voluntary but in case you will complete the study you will receive XXX for your participation in a one-hour experiment. In case you decide to leave the experiment before its completion for reasons that are not associated with direct discomfort caused by the study you will not receive any compensation.

Privacy and data protection
The data collected in this study are confidential and will be accessible only to the research team. Any publication that will come out of this study will never include personal information and will only include summary statistics. It would be impossible to link between your personal data and general statistics.

Withdraw and discomfort
You have the right to stop your participation at any time if you wish to do so for whatever reason it may be.
If during the study, you feel discomfort of any kind please make sure to inform the experimenter. In such a case, the experiment will be stopped and you may withdraw from the study.

Thank you very much for your cooperation. Your participation is greatly appreciated.
In case you have any further questions that are not covered in this information sheet please contact the experimenters or the PI at ______________________________

Regards,
The research team

A.5 Additional information

Name of Research project: ....

Name and position of applicant: ....

1. Please describe how you are going to ensure that your participants have the capacity to understand what it means to take part in the project and give consent.

2. Please describe how you will deal with incidental findings that indicate that the study compromises safety or health of participants, experimenters, or others?

3. Please specify the methodology for anonymizing personal data

4. Please clarify, if relevant, how you will deal with dissemination activities of footage with experiments of human participants.

5. In case of on-road studies: Please specify the measures that you will take to ensure that participants, experimenters and test drivers are safe?