PANACEA
FITNESS TO DRIVE

PracticAl and Effective tools to moNitor and Assess CommErciAl drivers' fitness to drive

Grant Agreement Number: 953426

D6.2: Evaluation framework, plans and material – an update

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Legal Disclaimer

Executive Summary

This deliverable presents the evaluation framework, plans and material for all data collections connected to work package 6 (WP6) of the PANACEA project. It describes the objectives of the studies and how they will be realised. The purpose of the PANACEA evaluation framework is to create a common framework to be used in all studies to make sure the data are collected in a way that makes it possible to consolidate the results at the end and to provide what is needed for impact analysis (WP7). The first version of the deliverable (D6.1: 'Evaluation framework, plans and material´) had its focus on setting the framework and the work process. In this updated version, the focus is on the evaluation protocols for all studies, including templates for the pilot sites, questionnaires to use, key performance indicators (KPI), log files to use, crucial timelines, etc. The experimental plans are described per pilot site and type of evaluation activity. The key content of D6.2 is structured as follows:

Chapter 1 is the introduction to the deliverable, specifying its purpose, the intended audience, and interrelations with other project activities. **Chapter 2** introduces the project objectives related to the WP6 data collections. **Chapter 3** provides a brief overview of each Use Case and **Chapter 4** presents the various studies within the project including descriptions of the main actors, environment, vehicles, PANACEA sensors/technologies, and countermeasures. **Chapter 5** describes the PANACEA evaluation framework. Chapters 6-15 then describe the steps defined in the evaluation framework. **Chapters 6-11** include the planning phase and present the Use Case Scenarios, Research Questions, Key Performance Indicators, study designs, data gathering tools, and data analysis plan. **Chapters 12-13** describe the implementation phase, including pilot site preparations, and data collection. **Chapters 13-15** describe the data analysis phase and includes chapters about data delivery, data analysis, results reporting, results consolidation, and impact assessment. Lastly, **Chapter 16** provides the conclusions of the deliverable.

The deliverable presents both a horizontal perspective of the pilot sites as well as more detailed descriptions of what will be included in the different studies. The main text of the deliverable provides an overview of all studies and evaluations within PANACEA. Research questions and KPIs are defined for each study (Appendix III). The general data gathering tools (objective and subjective) are identified. The questionnaires used for the evaluations are included in Appendix IV. A set of guidelines on practicalities and ethical aspects to take into consideration before and during data collection are presented. Experimental plans for all WP6 data collections are included as appendices to the deliverable (Appendix II).

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Other authors involved:	Anna Anund (VTI), Katerina Touliou (CERTH), Selpi (Chalmers), Ashleigh Filtness, Rachel Talbot (Lough), Beatriz Delgado, Iosu Erauskin (Datik), Davide Shingo Usami (CTLUP), Sandra Trösterer, Cyril Marx (VIF)
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Abbreviation List

Abbreviation	Definition
ADAS	Advanced Driver Assistance System
AIT	Austrian Institute of Technology GmbH
AUDIT	Alcohol Use Disorders Identification Test
AV	Automated Vehicle
BMM	Biomathematical Model
BrAc	Breath Alcohol Content
CAN	Controller Area Network
CDC	Centers for Disease Control and Prevention
CHT	Commercial Health Toolkit
CONSORT	Consolidated Standards of Reporting Trials
DBL	Deep Blue S.r.l.
DDA	During Driving Assessment
DoA	Description of Action
DPIA	Data Protection Impact Assessment
DSS	Decision Support System
EB	Ethics Board
ECG	Electrocardiography
EEG	Electroencephalography
EOG	Electrooculography
EU	European Union
FESTA	Field opErational teSt supporT Action

Abbreviation	Definition
FOT	Field Operational Tests
GDPR	General Data Protection Regulation
GSR	Galvanic Skin Response
KPI	Key Performance Indicator
KSQ	Karolinska Sleep Questionnaire
KSS	Karolinska Sleepiness Scale
MS	Milestone
OBJ	Objective
ODA	Off Duty Assessment
OM	Outcome Mapping
ONPDA	On site & Pre-Driving Assessment
PTW	Powered Two-Wheeler
PWA	Pulse Wave Analysis
QoL	Quality of Life
RCT	Randomized Controlled Trials
RQ	Research Question
RSA	Roadside Assessment
SATI	SHAPE Automation Trust Index
SD	Standard Deviation
SE	Sensitivity
SP	Specificity
STROBE	STrengthening the Reporting of OBservational studies in Epidemiology

Abbreviation	Definition
SUS	System Usability Scale
TAC	Transdermal Alcohol Content
TAQ	Technology Acceptance Questionnaire
UC	Use Case
UCS	Use Case Scenario
UCscr	Use Case script
VIF	Virtual Vehicle research GmbH
VRU	Vulnerable Road User
VSS	VTI acute Stress Scale
VTI	Swedish National Road and Transport Research Institute
WP	Work Package

1 Introduction

This deliverable called **Evaluation framework, plans and material – an update** presents a clear framework for all planned data collections needed for the evaluation work of the PANACEA project. The PANACEA project will create commercial driver-oriented, health-based and Use Case (UC)-driven health monitoring and assessment methodologies and technical solutions, i.e., 'Commercial Health Toolkits' (CHT) and develop an effective strategic, tactical, and operational cloud-based coaching & supporting solution for commercial drivers. The PANACEA solution, including the CHTs and countermeasures' solutions will be evaluated in an iterative process. The data collections needed for the evaluations include both simulator studies, real-world evaluations, and roadside assessments. All material needed to complete the data collections, such as templates to be filled in, questionnaires to use, performance criteria, indicators, log files to use, timelines, etc. are be defined here. In the previous version of the deliverable, D6.1, a general evaluation framework was be established and the principles for the data gathering tools were developed to be applicable to all the project's UC. Based on the general framework, individual evaluation strategies have been designed that fulfil the requirements of each individual data collection. In this updated deliverable, detailed experimental plans are included for all PANACEA studies. The planned data collections have a variety of study designs and purposes but nonetheless the methodology is kept as similar as possible across pilots. To achieve a harmonized way of collecting data and ensure good quality of the data collected, all studies follow the general evaluation framework developed in D6.1. This framework adheres to existing transportation frameworks (e.g., FESTA (Barnard et al., 2016)), but additionally incorporates components from clinical and experimental protocols, necessary to address the elements and dimensions of the evaluation objectives and the relevant project objectives. The deliverable provides a common template for harmonising and coordinating all tests with drivers at an early stage, to optimise the consolidation that will be made in A6.5.

Three types of studies are included in the PANACEA project; 1) simulator and roadside studies aiming to refine the algorithms developed and offer the possibility of repetition of measures to reach the targeted sensitivity (SE) and specificity (SP) levels per CHT identified in the project, 2) validation and assessment pilots for evaluation of the CHTs at three pilot sites, and 3) countermeasures' pilots where evaluation of both the content and the actual online coaching system will be performed in parallel with the CHT pilots.

1.1 Purpose of the document

The purpose of the Evaluation framework, plans and material – an update is to create a common framework to be used in all WP6 data collections, to make sure the data are collected in a way that makes it possible to consolidate the results of the pilots' evaluations and to provide what is needed for impact analysis. The deliverable will describe what kind of data that will be collected, what the purpose is, how the data will be used in the project, and by whom it will be collected.

The study designs will differ between pilots, depending on the specific aim of each data collection. However, the Evaluation framework, plans and material – an update will ensure that a common process for planning and implementation of data collection, analysis of data, and results reporting will be followed at all pilot sites.

The first version of the Evaluation framework, plans and material defined the evaluation framework, its dimensions and the overall KPIs. Moreover, it also included the first version of the pilot plans and selections of data collection tools. The update of the deliverable, includes the detailed evaluation protocols, templates for pilot sites (see Appendices), questionnaires to use, performance criteria, indicators, log files to use, crucial timelines, etc. In addition, the final pilot and experimental plans are defined and described per pilot site and type of evaluation activity.

1.2 Intended Audience

The intended audience of the document is both internal to the project and external. The deliverable serves as a manual for the pilot sites in their planning and conduction of data collections. It is also an informative document to describe to external stakeholders how the PANACEA solution will be evaluated in the project.

1.3 Interrelations

The data collections covered by the Evaluation framework, plans and material – an update deliverable are highly interrelated to many other activities in the PANACEA project. Firstly, WP1 developed the UCs and Use Case Scenarios (UCS) to be evaluated by WP6. Secondly, the main purpose of the deliverable is to provide the framework for the evaluation work of WP3, WP4, and WP5. Therefore, there will be extensive collaboration between WP6 and WP3, WP4 and WP5. All WP6 data collections are dependent on verification and validation performed in WP2 and WP4 before final evaluation of the PANACEA solution can start. A6.2 will collect data to improve/create algorithms of WP3 and improve/define the thresholds for each impairing state addressed. A6.3 and A6.4 deals with the PANACEA solution validation and assessment and will thus depend on the development of various parts of the PANACEA solution performed in WP2, WP3, WP4, and WP5. The results of WP6 will then be fed to WP7 for the impact assessment.

2 Project objectives

PANACEA aims to create a holistic pre-, during and roadside driving ability monitoring and assessment system. The system will reliably and efficiently assess the physical, cognitive, and psychological Fitness-to-Drive of commercial drivers. In cases of impairment, a complementary cloud-based countermeasures and coaching tool will deploy appropriate solutions targeting drivers, operators, and enforcement. Below, the objectives that are directly and indirectly relevant to the WP6 are included.

The objectives directly relevant to WP6 are the following:

OBJ3: Evaluate the usefulness, ease-of-use, satisfaction, and acceptance of the CHTs across 3 UC-driven Pilots, considering gender specificities (WP6).

OBJ4: Evaluate an effective strategic, tactical, and operational cloud-based coaching & supporting solution for commercial drivers combating driver impairment (WP5 & WP6).

The objectives that are indirectly relevant either by being a prerequisite for the WP6 studies, by using data collected during the WP6 studies or by use of the inferences drawn are OBJ1, 2, 5, and 7.

OBJ1: Create commercial driver-oriented, health-based and Use Case (UC)-driven health monitoring and assessment methodologies and technical solutions (i.e., 'Commercial Health Toolkits'; CHTs). The platform will be developed in WP2, the content and the algorithms in WP3 and the actual systems and the Decision Support System (DSS) in WP4.

OBJ2: Estimate the sensitivity, specificity, effectiveness, and operability of CHTs for alcohol, licit (benzodiazepines), illicit (methadone) drugs, fatigue, stress and cognitive load. The CHTs will cover before/ after/ during shifts as well as on-site (for fleet operators) and roadside (for enforcers; WP5 & WP6).

OBJ5: Create a new paradigm in Fitness to Drive (Fitness to Drive 2.0), considering new technologies and commercial vehicles' varying automation levels (WP3, WP4, WP5 & WP6).

OBJ7: Assess the safety, socioeconomic and Quality of Life (QoL) impacts of CHTs and relevant monitoring, assessment and coaching solutions and policies Europe-wide (WP7).

3 Use cases

Use Cases in PANACEA comprise the technologies, the actors involved, the vehicles they drive, and the impairments addressed at each of the three pilot sites (Sweden in UCA, Greece in UCB, Spain in UCC). They were developed in WP1 and a more detailed description of the UCs can be found in D1.1: 'Use Cases'. The driver clusters addressed per UC are shown below.

Use Case (UC)	Target drivers
A	Bus/shuttle drivers
B	Powered Two-Wheeler (PTW) courier delivery riders
B	Taxi drivers
C	Coach drivers
C	E-truck driver (refuse/rubbish/garbage collection)

3.1 UCA

The target population in UCA is bus drivers who are also safety operators for autonomous shuttles. The focus is on the safety during shuttle operation in Linköping, Sweden. Key considerations are the impact of shift work, task related fatigue, and the need to interact with Vulnerable Road Users (VRU). It is intended that the PANACEA system will detect fitness-to-drive prior to starting work as this is the priority to ensure people are fit to drive when starting work. In addition, it is necessary to take into consideration that the task is very monotonous, so fitness (particularly alertness) needs to be maintained throughout the shift. There is also a need to prepare drivers ahead of their future shifts. To make this happen also the manager at the bus operator is important. They need knowledge on the drivers' status and how to plan to support the drivers and avoid unnecessary demanding shifts.

Priority: off-duty (lifestyle, to ensure fitness prior to starting the work shift), on-duty (pre-driving, the driver is at work and should be assessed before they are allowed in the vehicle), on-road (in the vehicle while driving as a guidance/assistance system).

3.2 UCB

Taxi drivers and courier service riders who work in the prefecture of Thessaloniki, Macedonia, Greece are targeted. Key considerations are the impact of stress, fatigue, alcohol, and (il)licit drugs consumption. Fitness will be assessed across all work shift phases with emphasis pre- and during the shift. It is very important to accommodate for the conditions that both types of professionals work in. For example, taxi drivers often drive in unfamiliar and not pre-scheduled routes, whereas courier service riders often know the delivery routes at the beginning of their shift. However, they both experience dense urban traffic and the related risks. Taxi drivers are often self-employed and freelancers, whereas the courier service riders are employees, as is the case with the target populations in the other two Use Cases.

Priority: on-duty (pre-driving, the driver is at work and should be assessed before they are allowed in the vehicle), on-road (in the vehicle while driving as a guidance/assistance system).

3.3 UCC

The target population at this UC is truck and coach drivers working in San Sebastián and Barcelona, Spain. On the one hand, workers from a company dedicated to the collection of rubbish using heavily instrumented vehicles such as the ieTruck. On the other hand, bus drivers are distributed among two bus companies with different service and regulation goals.

Key considerations in this UC are the impact of shift work and the impact of different states of driver impairment caused by both stress and fatigue. In UCC it is intended that the PANACEA system detect fitness before starting work since this is the priority to ensure that people are fit to drive when starting work. There are differences in the daily routines of each type of driver (truck driver, regular bus driver, long-distance bus driver) and this has been taken into account throughout. Different results are expected for the different types of drivers, not because of the creation of details and characteristics of a study within the UC, but because of the idiosyncrasy of the task itself. For example, for regular bus drivers, it is necessary to understand that the task is very monotonous, so fitness (especially alertness) needs to be maintained throughout the shift. For garbage truck drivers, the task is done on the night shift, which means extra effort to stay alert. In this case, it is essential to prepare the drivers before their future shifts. The UCC includes the conditions of urban, interurban and rural roads.

Priority: Off-duty (lifestyle, to ensure fitness before starting shift), On-site (before driving, driver is at work and must be screened before being allowed into vehicle), On-duty (in the vehicle while driving as a guide/assistance system).

4 Pilot sites and studies

There are three main pilot sites in the project, related to the Use Cases A, B and C. In addition, a roadside pilot will be performed. Below is a description of each site including a description of the objectives, main actors, environment, vehicles, PANACEA sensors/technologies used to measure driver impairment, and countermeasures developed and tested. Simulator and roadside studies will be performed and serve the purpose to develop and test the PANACEA system. Real-world and semi-real-world studies will then be performed at the pilot sites to evaluate the system in operational settings. In this chapter an overview of the studies is presented, and the detailed experimental plans can be found in Annex II.

4.1 UCA

The focus in PANACEA is to develop and evaluate a system that integrate sensors used to detect and avoid driving under impairment. Here alcohol/ drug use, fatigue and stress are of major interest, and the countermeasures that are relevant from strategical, tactical and operative level.

The A6.2 simulator study will be performed in a driving simulator at the Swedish National Road and Transport Research Institute (VTI) premises in Linköping, Sweden to enable safe testing of driving under the influence of alcohol. Real-life data collection in the A6.3 and A6.4 study will be conducted with autonomous shuttles in the nearby University campus and residential area.

4.1.1 Simulator study (UCA-S)

The objectives are to learn more about how moderate amounts of alcohol in the evening affects night sleep and next day driving performance and based on this develop a first version of a biomathematical model of fatigue (WP3) that takes next-day effects of alcohol into account.

The data collection needed will be done at VTI using two fixed based driving simulators in parallel. The simulators have three computer screens and a vehicle mock-up, see Figure 1. A total of 30 male drivers aged 25-50 years old will be included in the study and the data will be used to update the fatigue algorithms with data on alcohol sleep on fatigue development. The scenario will include both urban and rural road driving.

Figure 1. *Driving simulator environment.*

The PANACEA sensors to be included are: AIT smartPWA (Pulse Wave Analysis) and Fitbit.

4.1.2 Real-world pilot (UCA-R)

The objective is to evaluate and assess the CHT-A and its countermeasures addressing both autonomous shuttle safety drivers and the managers.

The evaluation will be done in Linköping, Sweden at a site that consists of a 4.1 km long route including roads with both mixed traffic, meaning interaction with other motorized vehicles, but also a dedicated area with only pedestrians and cyclists allowed, see Figure 2. It covers the Linköping University campus and a residential area called Vallastaden. Two EasyMile autonomous shuttles using 13 bus stops will be included. The service is up and running 7 days a week according to a frequency-based timetable.

Figure 2. *An overview of the Linköping site (UCA). Left: route, Middle: EasyMile shuttle Right: EasyMile shuttle in Vallastaden.*

At the site there are 8 safety drivers working approximately 60 percent of their time as shuttle operators and the rest as city bus driver and/or tram driver. In addition, 2 managers will be involved. The impairments in focus are alcohol/ drug use, fatigue and stress, and the countermeasures that are relevant cover both strategical, tactical and operative level.

The sensors to be included are: DATIK FitDrive, AIT smartPWA, Senseair Wall, Leitat biosensor, Fitbit, and BMM.

For UCA safety drivers the selection of countermeasures defined in A5.2 are shown in Table 1 and countermeasures for managers are shown in Table 2.

Table 1. *Selected countermeasures for drivers.*

	Operational	Tactical	Strategic
UCA	**-Caffeine and napping advice for fatigue when sleepiness signs are detected** -Self-management of stress/cognitive load during shift	**-Raising awareness of fatigue for drivers, providing sleep/recovery advice before/after work** *-Advice about alcohol use before work (not during shift) e.g., evening before*	**-Lifestyle coaching relating to sleep and fatigue** (could inc. alcohol) -Lifestyle coaching for optimising rest (off duty) time in terms of reducing stress and related fatigue
UCB	**-Self-management of stress/cognitive load during shift (could inc. headway management)**	**-Advice about licit drugs prior to shift (taken the night before a morning shift or in the morning of**	**-Lifestyle coaching relating to stress and cognitive load**

	Operational	Tactical	Strategic
	-Guided breathing exercises	**a morning shift) focus on immediate and residual effects**	*-Lifestyle coaching relating to prescription drugs*
UCC	**Providing message, auditory, visual and/ or haptic warning/alert to a driver and operator that fatigue has been detected** -Self-management of stress/cognitive load during shift (could inc. headway management) -Caffeine and napping advice for fatigue when sleepiness signs are detected	Raising awareness of fatigue for drivers, providing sleep/recovery advice before/after work	**Lifestyle coaching for optimising rest (off duty) time in terms of reducing stress and related fatigue** Lifestyle coaching relating to sleep and fatigue

Table 2. *Selected countermeasures for operators/managers.*

	Operational	Tactical	Strategic
UCA	-Changing driver due to fatigue **-Changing driver due to alcohol** -Advice to operator on how to action results of DATIK pre-questionnaire (e.g., change driver/nap/caffeine) *-Providing facilities for rest breaks*	**-Advice/tools for Scheduling and how work is distributed within a shift** -Training on how to use and interpret PANACEA system -Training for managers in how to identify stress in drivers/when driving	**-Training and education on impact of alcohol and fatigue on driving** -Training and education on impact of licit/illicit drugs on driving *-Driver impairment risk management system* *-Establishing open culture to encourage reporting of PANACEA related impairment*
UCB	**-Advice to operator on how to action results of DATIK pre-questionnaire (e.g., change driver/nap/caffeine)**	-Training on how to use and interpret PANACEA system *-Medical assessment when drivers join company - licit drugs*	**-Training and education on impact of licit/illicit drugs on driving** **-Training and education on medication management**

	Operational	Tactical	Strategic
			-Training and education on impact of alcohol on driving
UCC	**-Changing driver due to fatigue** -Changing driver due to alcohol -Advice to operator on how to action results of DATIK pre-questionnaire (e.g., change driver/nap/caffeine) *-Providing facilities for rest breaks*	**-Training for managers in how to identify stress in drivers/when driving** -Training on how to use and interpret PANACEA system	**-Training and education on impact of fatigue on driving** -Training and education on impact of alcohol on driving *-Driver impairment risk management system* *-Establishing open culture to encourage reporting of PANACEA related impairment*

4.2 UCB

Two pilot sites will participate in the studies connected to UCB. The A6.2 studies will be performed at the site in Thessaloniki, Greece (CERTH) and at the site at Austria (ViF). The real-life pilots (A6.3 and A6.4 activities) will be conducted on the simulator due to ethical and legal restrictions (potential consumption of alcohol and drugs will be included) and for participants to experience holistically the PANACEA solution across impairments and states in one context. Further, for continuous monitoring technologies (i.e., FitDrive and BACtrack skyn wristband) small studies will be conducted in the area of CERTH premises. UCB includes the CERTH and ViF driving simulators, the CERTH riding simulation laboratories (A6.2) and the CERTH premises (A6.3 and A6.4).

The infrastructure for the simulator pilots are the two passenger car simulators in CERTH and ViF premises, the motorcycle simulator at CERTH and an instrumented passenger car and motorcycle for the real-life tests inside the CERTH premises.

Fatigue, alcohol consumption and stress will be addressed in A6.2 pilots in Thessaloniki, Greece and distraction will be addressed in Austria. Fatigue and post-alcohol consumption state will be addressed in semi-real-life conditions in A6.3/A6.4 pilots and fatigue, stress, distraction, alcohol and drugs will be addressed only in simulated environment.

4.2.1 Simulator study 1 (UCB-S1a UCB-S1b)

The objectives are to collect data for the refinement of the algorithms developed in WP3 and to ensure that the selected levels for the impairing and driver states are meaningful and measurable with targeted accuracy, sensitivity, and specificity. This will be done both for passenger car drivers (n=20) and for Powered Two-Wheeler (PTW) riders (n=20) and hence two different types of simulators will be used, see Figure 3. The car driving simulator is a dynamic car simulator with a complete car (SMART) on a rotating platform. The riding simulator is a dynamic motorcycle simulator. The simulator dynamics allow five degrees of freedom (roll, pitch, yaw, handlebar extension and shortening). The visual system of the simulator employs three projection screens that cover the riders' field of view and an instrument panel with an LCD screen that presents information through the simulator Controller Area Network (CAN) bus and can be also used on a motorcycle.

Figure 3. *Driving simulator (left) and riding simulator (right).*

The environment will be peri-urban and urban and the impairments in focus will be fatigue, alcohol consumption and stress.

The PANACEA sensors to be included are: Datik FitDrive, AIT smartPWA, Senseair Wall and Go, BACtrack Skyn, Optalert, and GSR sensors.

4.2.2 Simulator study 2 (UCB-S2)

The objective with the simulator study at VIF is to evaluate different types of driver distraction (cognitive, visual) in different driving environments (city vs. highway) to collect data for the development of a multisensory fusion algorithm for detecting a distracted driver state. Both steering / use of the steering wheel and visual behaviour will be included. The environment will be an urban road and a highway. Twenty experienced drivers will participate in the trials. The simulator can be seen in Figure 4.

Figure 4. *Driving simulator that will be used in the study at ViF.*

The PANACEA sensors to be included are the AIT smartPWA and the DBL Neuromatics Toolbox.

4.2.3 Semi-real-world pilot (UCB-SR1 and UCB-SR2)

The objective is to evaluate the performance and user experience of the holistic system mostly in a simulated environment to focus on the PANACEA solution performance and secondarily in a semi-real life condition considering driver impairments caused by stress, alcohol and fatigue, distraction, drugs as well as the countermeasures use and compliance.

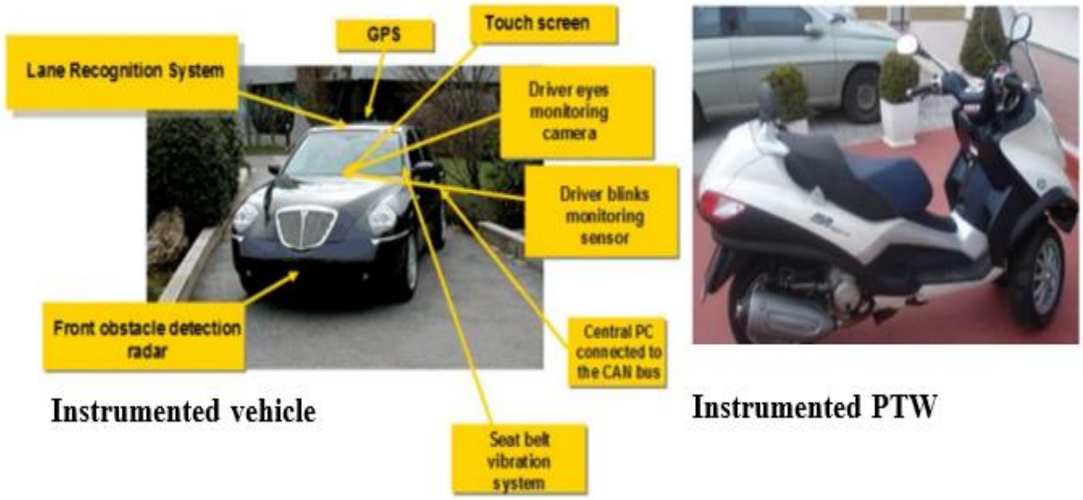

Figure 5. *Instrumented vehicle and instrumented PTW to be used at the test area in UCB.*

The environment will be real life testing in a controlled and closed traffic area with riders **(UCB-SR1)** and taxi drivers **(UCB-SR2)**. An instrumented vehicle and a motorcycle will be used, see Figure 5. Tests with FitDrive (fatigue) and BACtrack skyn wearable (alcohol) will be conducted in the CERTH area, whereas all will be conducted in the CERTH riding and driving simulators (same as in UCB-S1) for ethical and legal reasons. There will be 20 taxi drivers and 20 delivery service riders participating in the simulator studies and 10 (in total) for the smaller-scale semi-real-life tests on CERTH premises.

The PANACEA sensors to be included are: DATIK FitDrive, AIT smartPWA, ViF Driver Monitoring System, Senseair Wall and Go, BACtrack Skyn, Optalert, and GSR sensors.

The selected countermeasures for UCB drivers/riders and operators are presented in Table 1 and Table 2, respectively.

4.3 UCC

The UCC is focused on professional drivers and their managers running operations with garbage trucks and regular buses. This UC includes only real-world studies, and the data collection will be done in Barcelona city and also in San Sebastián (as a starting point of a route to Bilbao and to Paris as destinations).

The focus on driver impairments in Spain site are alcohol/drug use, fatigue and stress detection. There will be three data collections at two locations for the use case.

- The R1 site is an urban scenario in Barcelona with two garbage trucks.
- The R2 site will be interurban coach travel between cities (regular services that start in San Sebastián and finish in Bilbao).

- The R3 site will be a long-distance journey between two cities (starting in San Sebastián and finish in Paris).

The objective is to evaluate the PANACEA system with integrated sensors used to detect and avoid driving under impairment and the relevant countermeasures on strategic, tactical, and operative levels. In total, 4 vehicles will be included in the evaluations (2 trucks and 2 coaches).

The type of professional drivers in focus are three different groups, see Table 3.

Table 3. *Driver profiles included in UCC evaluations*.

SITE	VEHICLE	DRIVER	ITINERARY	SCHEDULE	Kms	OTHER
R1	ieTruck	Professional driver	From garage - urban - unloading point - urban garage	From 21:00 to 4:00	75/100 kms	Low speed, multiple stops
R2	Irizar i6s - MAN	2 - professional driver	Garage - Donosti - Bilbao (relief) garage	Morning shift 5:30/6:00/6:30 (depends) Afternoon shift 12:30/13:00/13:30 (depends)	450 kms	High speed, monotonous driving
R3	Irizar i6s	Professional driver	Garage - Donosti - París - garage	8 hours shift Morning shift starting at 5:30	420 kms	High speed, long distance

The sensors to be used are: DATIK FitDrive, ViF Driver Monitoring System, AIT Smart PWA, Senseair Wall and Go, and LEITAT biosensor.

The selected countermeasures for UCC drivers and operators are presented in in Table 1 and Table 2, respectively.

4.3.1 Real-world pilot - UCC-R1

Truck drivers drive an ieTruck (FCC) picking up garbage following a special service line in Barcelona see Figure 6. The drivers work night shifts only. In total there will be 2 trucks equipped.

Figure 6. *Garbage Irizar truck in Bilbo Donosti*

4.3.2 Real-world pilot UCC-R2

Bus drivers drive a bus service in Bilbo-Donostia with one departure every half hour from 6 am to 10 pm. Each service is 1 hour and 15 minutes. The drivers' shifts start and end depending on the first service assignment. There will be 2 drivers involved divided into morning or afternoon shift. There will be one coach equipped.

4.3.3 Real-world pilot UCC-R3

Two bus drivers drive a coach as a long journey bus service with a starting point in San Sebastián going to Paris. They start 9:30 and arrive the destination at 20:10 the same day. They rest in Paris and start next morning at 08:30 for the return to San Sebastián. Here, 8 drivers will be involved, and they are grouped 2 in each group. In 2 of the groups, they work a fixed schedule with 4 days in a row and rest 2 days. Those days are driven by drivers in the remaining group. There will be one coach equipped.

4.4 Roadside study

Roadside assessment is an assessment normally conducted by an enforcer (i.e., police/authority) by asking a vehicle to stop to the side of the road, so the driver/ rider to be tested. The roadside study is related to the evaluation of the sensors developed for alcohol and drug testing at roadside. The objective is to evaluate the level of agreement between SENSEAIR’s (alcohol detection) and LEITAT’s (drugs) devices and the commercial devices currently in use by the Norwegian Police for roadside assessment (Dräger for alcohol and drug testing). Test will be performed on public roads in Norway.

The alcohol roadside testing procedure in Norway is based on the regulation that a Breath Alcohol Content (BrAC) value >0.1 mg/L is seen as a positive sample and the driver needs to follow the police officer to the police station for additional breath or blood test. For drugs a similar procedure is followed, but here with different cut off values depending on the drug. In situations with positive tests the police also perform a “sign and symptom” test before bringing the driver to the police station for further blood testing.

In PANACEA the same procedure as normal will be followed, but with the PANACEA devices (SENSAIR & LEITAT) used in parallel with the normal devices as the police use today. Action taken due to positive answers will only be based on the devices the police normally use for testing, not the PANACEA sensors. Countermeasures including training of monitors and enforcement authorities are presented in

Table **4**. The target number of drivers to test is 600 for alcohol and 100 for drugs.

Table 4. *Selected countermeasures for enforcers.*

	Operational	Tactical	Strategic
Alcohol	**-Roadside testing**	**-Training for enforcement offices for use of the PANACEA system** -Awareness campaign for roadside testing **-Provide guidance to operators/drivers**	-Influence on regulatory framework -Influence on policy documents
Licit / illicit drugs	**-Roadside testing**	**-Training for enforcement offices for use of the PANACEA system** -Awareness campaign for roadside testing **-Provide guidance to operators/drivers**	-Influence on regulatory framework -Influence on policy documents

5 Evaluation Framework

The framework developed within the PANACEA project incorporates components from several of the frameworks reviewed in D6.1. The FESTA methodology was used as the foundation and the various steps in the evaluation process were adapted to suit the purpose of the PANACEA project. The development of the PANACEA solution is an iterative process where results from WP6 data collections are fed back to WP3, WP4, and WP5 to refine the solution before the final evaluation (Figure 7). Technical validation of the systems used in the data collections will be performed before the start of each data collection. The technical validation is described in chapter 12.4 and the validation protocol for simulator studies is included in Appendix I. The results will be fed back to the relevant activity responsible for the development or integration of the technology. Any issues discovered will be resolved before proceeding with the evaluation process. The results of the technical validations will be reported in milestones M15, M16, and M17. Results from the simulator and roadside data collections will be utilized to refine the algorithms developed in WP3. The conduction of A6.2 will happen in close collaboration with respective WP3 teams. The PANACEA solution validation and assessment pilots (A6.3) will conduct the validation tests to assess the readiness of the CHTs in collaboration with WP4 prior to the final evaluation at the pilot sites. In contrast to the technical validation, this validation will focus on the performance of the full PANACEA solution in operation, not the performance of individual sensors or parts. The collected data will be used to improve the technologies and their integration to CHTs and resolve any technology issues. Furthermore, the CHTs' assessment pilots will be also organised, monitored, and executed in A6.3, to provide data for the final evaluation and impact assessment of the PANACEA solution. Activity A6.4 is about the realisation of the countermeasures' pilots. The evaluation of both the content and the actual online coaching system will be performed at the three pilot sites, in parallel with the A6.3 studies. The data collected will be fed back to WP5, to further improve the system.

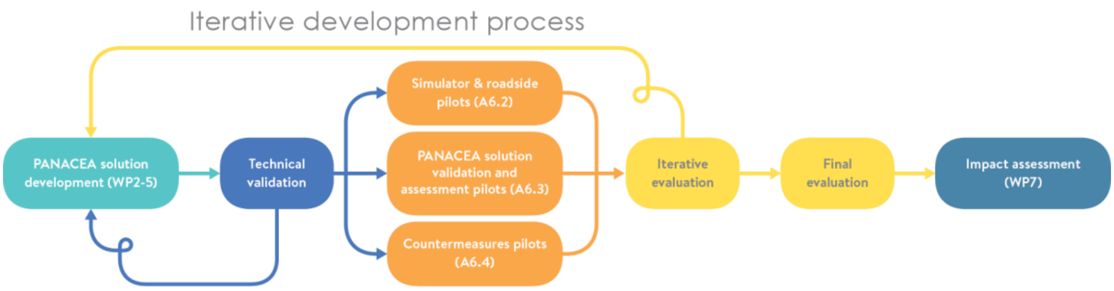

Figure 7. *PANACEA Iterative development process.*

The various data collections in WP6 used for the iterative development and for the final evaluation and impact assessment will follow the methodology of the PANACEA evaluation framework (Figure 8). The process is divided into three phases; planning, implementation, and analysis and reporting. Each box in Figure 8 represents a step to follow in the evaluation process. The steps are described as sequential steps in a linear way, where each step provides the necessary input for completion of the next step and the arrows show the dependencies between different steps. However, there might be a need to perform several steps in iteration during the process. As an example, there might be a need to revisit and adjust the study design after setting up the data analysis plan if it is discovered that other types of data are needed.

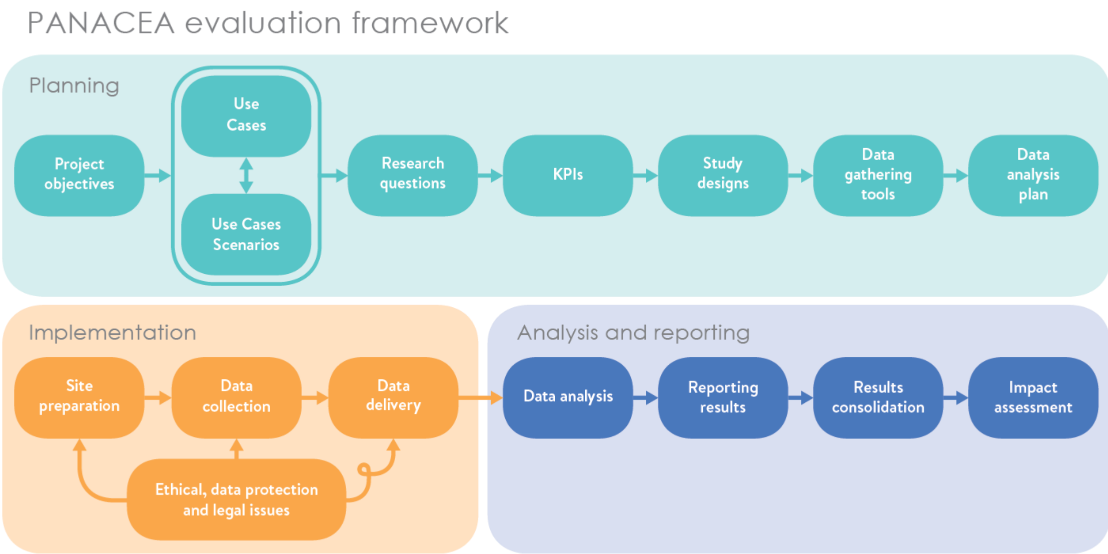

Figure 8. *PANACEA Evaluation Framework.*

The steps of the PANACEA framework are explained in the chapters below. Each step has its own chapter with a general description and an overview of how this will be implemented in the PANACEA project. The detailed experimental plans with descriptions of how to carry out the data collections at the sites are included in Appendix II. In the main deliverable, an overview of the planned data collections at each site is presented.

Data collection in the first simulator study (UCA-S) started in month nine (M9) of the project (January 2022). Simulator study UCB-S2 data collection was conducted in M18-M20 (October to December 2022). The remaining A6.2 simulator study, connected to UCB, will be conducted during the spring of 2023. Roadside assessments will be performed in two separate data collections, one during the autumn 2022 and one during the spring of 2023. Real-world and semi-real-world studies performed within A6.3 and A6.4 will follow thereafter. The main data collections used for the final evaluations will be performed between January and August 2023 (M21-M28). Preparations will start earlier and analyses and results consolidation will continue until M32 (December 2023). An overview of the timeline for all planned studies is presented in Figure 9.

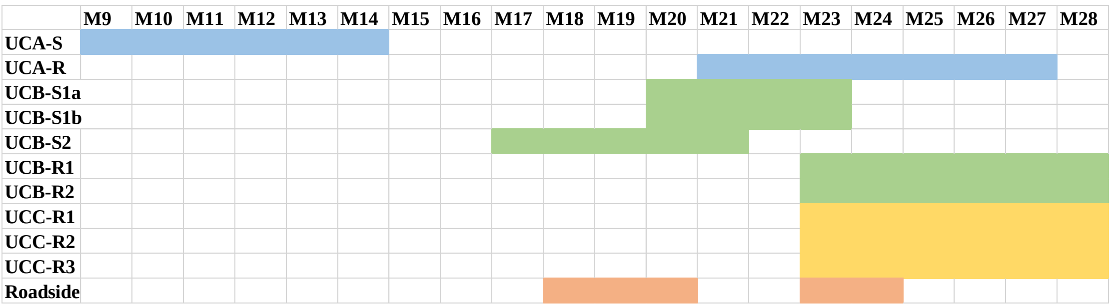

Figure 9. *Timeline of WP6 data collections.*

6 Use case scenarios

As defined in D1.1, the **Use Case Scenario** is a sequence of interactions happening under certain conditions, to achieve the primary actor's goal, and having a particular result with respect to that goal. The main purpose of use case scenario is to present in a detailed and clear and easy-to-learn way, the functional requirements of a system.

The following table presents the matching between the UC scenarios and scripts, as described in D1.1 and their connection with the Use Cases. Most of the UC scenarios apply to all UCs, because their implementation is horizontal. Those that target the technologies (CHTs; first column) do not apply to all UCs. Please refer to D1.1: 'Use Cases' for detailed descriptions of the Use Case scenarios.

Table 5. *Matching between Use Cases (UC) and Use Case Scenarios (UCS) or Use Case scripts (UCscr).*

CHTs and Technologies	UCs	Working shift flow	UCs	Administration, backend, and actors-oriented UC scripts	UCs
UCS01: FitDrive (Primary) – DATIK	**All**	UCS12: Baseline assessments	**All**	AII.1 UCscr17: Operators	**All**
UCS02: Alcohol sensor (Primary)– SENSEAIR	**All**	UCS13: Pre-Driving Assessment (incl. on-site) (ONPDA)	**All**	AII.2 UCscr18: Technology/ Service provider	**All**
UCS03: (Il)Licit drugs biosensor (Primary)- LEITAT	**All**	UCS14: During Driving Assessment (DDA)	**All**	AII.3 UCscr19: WP5 Development Team Countermeasures' specialist (responsible for the content of CCS)	**WP5/ outside UCs**
UCS04: - Smart Pulse Wave Analysis (PWA) device – AIT	**UCA/UCB**	UCS15: Roadside Assessment (RSA)	**All (but tested only in Norway)**	AII.4 UCscr20: Enforcer	**Norway / outside UCs**
UCS05: Steering wheel angle algorithm (SWA) and vehicle parameters (Primary)- ViF	**UCB**	UCS16: off duty Assessment (ODA)	**All**	AII.5 UCscr21: Administrator	**All**
UCS06: DBL index (Secondary) - DBL	**UCB**		-	AII.6 UCscr22: Business rules	**All**

CHTs and Technologies	UCs	Working shift flow	UCs	Administration, backend, and actors-oriented UC scripts	UCs
UCS07: BACtrack Skyn (Secondary) – VTI and CERTH	**UCB**			AII.7 UCscr23: General actor registration/ authentication/ login (with failures) and creation of profile	**All**
UCS08: Fitbit wrist band (Secondary) – VTI	**UCA**			AII.8 UCscr24: Feedback module	**All**
UCS09: Biomathematical model (BMM; Primary)– VTI	**UCA**			AII.9 UCscr25: Communication module among core actors (optional)	**All**
UCS10: Optalert and GSR system (Secondary) – CERTH	**UCB**			AII. 10 UCscr26: Errors (as exceptions) handling (closely related to UC20 and this a system and not a business UC scenario- Diagnosis procedures)	**All**
UCS11: Cloud based Countermeasures ’ system (Primary) – CTLup	**All**				

7 Research questions

The research questions of the PANACEA project are related to the impact of the final PANACEA solution and to the development of specific technologies. The research questions were derived both from the Use Case Scenarios developed in WP1 (bottom-up approach) and by identifying the most relevant impact areas related to the overarching project objectives (top-down approach). As part of activity A6.1 and A2.5 in WP2, all PANACEA partners were asked to list question(s) that are of interest to them from their organisation's point-of-view, from their WP(s)' point-of-view, and from what they know would be important towards improving the health of professional transport workers.

To enable processing of the collected questions into research questions in WP6, a number of criteria of what make a good research question were defined. A good research question (RQ) must be clear, not too broad, and feasible to do within project time and budget. Further, a good RQ requires research and analysis to answer, and is of interest to partners and traffic safety community and useful for e.g., professional transport workers and community. Last but not least, the RQ must be measurable. With the general criteria of a good RQ in mind, several criteria related to the PANACEA project were added based on what was presented in the Grant Agreement, the sensors used in the project, etc.

With the general criteria and PANACEA specific criteria set, the selection and revision process began. The questions that were not clear, too broad, or not feasible do within the project time were not included for further process. The questions that were processed further, were checked by several people and reformulated (if necessary) to make them clear. They were grouped into four different categories related to the overall project objectives: validation of CHTs and technologies, evaluation of CHTs, evaluation of countermeasures, and impact. The RQs are also connected to the project KPIs. The short-listed RQs were then discussed and refined further in a workshop at the 4th plenary meeting in Greece.

The final set of RQs consist of 39 research questions. The high-level RQs that are relevant for all the UCs are presented in Table 6 below. Project objectives' numbers in Table 6 as they appear in GA. Specific research questions for each study can be found in the complete list of RQs in Appendix III.

Table 6. *High-level research questions (RQ) and their connection to KPIs and data gathering tools.*

Project objective	RQ Category	High-level RQ	Project KPIs	Data gathering tool
OBJ2	Validation of CHT and technologies	Do the relevant PANACEA sensors/systems detect targeted driver impairments effectively with high sensitivity and specificity?	KPI 2.1 Reliability of CHT, 2.2 Specificity of CHT, 2.3 Sensitivity of CHT, 2.4 Sensitivity and specificity of a sensor or combination of technologies	PANACEA sensors, reference sensors, subjective ratings of impairment
OBJ2	Validation of CHT and technologies	How is the performance of the PANACEA sensors compared to a reference measurement?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	PANACEA sensors & reference equipment

Project objective	RQ Category	High-level RQ	Project KPIs	Data gathering tool
OBJ2	Validation of CHT and technologies	Do the combined sensors improve driver state detection?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	PANACEA sensors (individual and combined)
OBJ2	Validation of CHT and technologies	Does the PANACEA integrated solution work in a real-life setting to detect impairment and deliver countermeasures?	KPI 1.2 Technical performance of CHT, KPI 2.1 Reliability of CHT, 2.2 Specificity of CHT, 2.3 Sensitivity of CHT	PANACEA platform (usage data), PANACEA sensors and subjective ratings of impairment
OBJ3	Evaluation of CHTs	Are the PANACEA sensors/systems accepted by the users?	KPI 3.4 Acceptance of CHT	Evaluation questionnaires
OBJ3	Evaluation of CHTs	Are the CHTs perceived as useful, satisfying, trustworthy, and easy to use?	KPI 3.1 Ease to use CHT, 3.2 Usefulness of CHT, 3.3 Willingness to use CHT, 3.5 Trust in CHT, 3.6 satisfaction of CHT	Evaluation questionnaires
OBJ4	Evaluation of countermeasures	What are the immediate effects of implemented countermeasures?	KPI 4.3 Effectiveness of a countermeasure	Questionnaires and PANACEA platform (usage data)
OBJ4	Evaluation of countermeasures	Is the PANACEA countermeasures system accepted by the users?	KPI 4.2 Acceptance of a countermeasure	Evaluation questionnaire
OBJ7	Impact	Does behaviour change/improve after the relevant countermeasure has been administered?	KPI 4.3 Effectiveness of a countermeasure, 7.4 CEA ratio or CBA ratio	Questionnaires and PANACEA platform (usage data)
OBJ7	Impact	Will the PANACEA countermeasures reduce driver impairment and improve the driver performance?	KPI 4.3 Effectiveness of a countermeasure, 7.3 N of saved lives, 7.5 QoL	Questionnaires (background and evaluation), PANACEA platform (usage data), and driving performance data from vehicles
OBJ7	Impact	Would it be possible to implement the PANACEA system in regular operation?	KPI 7.4 CEA ratio or CBA ratio	Focus group with different stakeholders

Project objective	RQ Category	High-level RQ	Project KPIs	Data gathering tool
OBJ7	Impact	Does the PANACEA system increase perceived (drivers) and reported (operators) safety?	KPI 7.1 Perceived (drivers) safety, 7.2, Reported (operators) safety	Questionnaires, focus group and PANACEA platform

8 Key Performance Indicators

In collaboration with the partners, the following table was defined including the final list of KPIs extracted from relevant impact targets from the Description of Action. Each KPI is matched to a project objective and, when available, the related impact target is added together with the type of KPI (Technology, Countermeasure, Impact). The KPIs are related to activities in several of the project WPs and not all of them are related to the data collections in WP6.

Table 7. *Project KPIs.*

Relevant project Obj	KPI_ID	Name of KPI	Relevant Impact targets (extracted from DoA)	Type
OBJ1	KPI 1.1	Number of CHTs created	Create one CHT per UC (i.e. A to C) and integrate them to the common architecture concept	Technology
OBJ1	KPI 1.2	Technical performance of CHT	Technical performance according to the CHTs' specifications, as they will be defined in WP2 > 85%	Technology
OBJ2	KPI 2.1	Reliability of CHT	Reliability, of relevant sensors/modules/subsystems >25% against relevant SoA.	Technology
OBJ2	KPI 2.2	Specificity of CHT	Specificity of relevant sensors/modules/subsystems >25% against relevant SoA.	Technology
OBJ2	KPI 2.3	Sensitivity of CHT	Sensitivity of relevant sensors/modules/subsystems >25% against relevant SoA.	Technology
OBJ2	KPI 2.4	Sensitivity and specificity of a sensor or combination of technologies	Sensitivity and specificity of relevant sensors/modules/subsystems >25% against relevant SoA.	Technology
OBJ3	KPI 3.1	Ease to use the CHT	Perceived satisfaction, usefulness, ease-of-use, acceptance >70% of users (drivers and operators)	Impact
OBJ3	KPI 3.2	Usefulness of CHT	Perceived satisfaction, usefulness, ease-of-use, acceptance >70% of users (drivers and operators)	Impact
OBJ3	KPI 3.3	Willingness to use CHT	Perceived satisfaction, usefulness, ease-of-use, acceptance >70% of users (drivers and operators)	Impact

Relevant project Obj	KPI_ID	Name of KPI	Relevant Impact targets (extracted from DoA)	Type
OBJ3	KPI 3.4	Acceptance of CHT	Perceived satisfaction, usefulness, ease-of-use, acceptance >70% of users (drivers and operators)	Impact
OBJ3	KPI 3.5	Trust in CHT	Perceived satisfaction, usefulness, ease-of-use, acceptance >70% of users (drivers and operators)	Impact
OBJ3	KPI 3.6	Satisfaction of CHT	Perceived satisfaction, usefulness, ease-of-use, acceptance >70% of users (drivers and operators)	Impact
OBJ3	KPI 3.8	Percentage of female pilot participants	At least 30% of the Pilot sample will be female	Impact
OBJ4	KPI 4.1	Number of countermeasures created	At least two countermeasures per level are created	Countermeasure
OBJ4	KPI 4.2	Acceptance of a countermeasure	The solutions are accepted by >75% of drivers, 70% operators and stakeholders.	Countermeasure
OBJ4	KPI 4.3	Effectiveness of a countermeasure	-	Countermeasure
OBJ4	KPI 4.5	Willingness to use a countermeasure	Perceived satisfaction, usefulness, ease-of-use, acceptance >70% of users (drivers and operators)	Countermeasure
OBJ5	KPI 5.1	Workforce representation	Able to detect Fitness to drive for commercial drivers (number and type of commercial drivers) for over 30% of current workforce	Impact
OBJ5	KPI 5.2	Number of recommendations relevant to EC Directives	At least two recommendations for each addressed and relevant Directive (e.g. 2002/15/EC, EU 3820/85 and 3821/85)	Impact
OBJ6	KPI 6.1	Number of specific recommendations	Propose at least 3 specific recommendations in relation to alcohol consumption, substance use and fatigue	
OBJ7	KPI 7.1	Perceived (drivers) safety	Perceived (drivers) and safety increases by 8%,	Impact
OBJ7	KPI 7.2	Reported (operators) safety	Reported (operators) safety increases by 8%,	Impact

Relevant project Obj	KPI_ID	Name of KPI	Relevant Impact targets (extracted from DoA)	Type
OBJ7	KPI 7.3	N of saved lives (on and off roads)	Saves lives on and off road (8%)	Impact
OBJ7	KPI 7.4	CEA ratio or CBA ratio	Cost Effectiveness Analysis (CEA) and Cost Benefit Analysis (CBA) will show a positive change and health, cost and transportation benefit when the drivers and transportation companies use the CHTs compared to existing tools/methods	Impact
OBJ7	KPI 7.5	QoL	QoL is estimated to increase by at least 2 points in Quality of Life in Years (QALY).	Impact

9 Study design

There will be a variety of study designs in the PANACEA project, depending on the objectives of each data collection. Most of them will use a within-subjects' design and common for all data collections is that they will have a control condition serving as a baseline for the validations and evaluation. The simulator and roadside studies are quite diverse with study designs tailored to fit the specific research questions connected to the study. The validation and assessment pilots and countermeasures' pilots are based on a repeated measures design, where the PANACEA system will be used repeatedly by the participating commercial drivers. In this chapter, an overview of the different study designs is presented. Detailed experimental plans for each can be found in Appendix II.

9.1 Simulator studies (A6.2) and roadside assessment

The simulator and roadside studies will collect data to improve and/or create the WP3 algorithms and to improve and define the thresholds for each impairing state addressed. The main outcomes or needs for improvements will be shared with WP2 and WP3 as described in chapter 14.1 Data delivery.

9.1.1 UCA-S

The specific aims of the UCA simulator study are to learn more about how moderate amounts of alcohol in the evening affects night sleep and next day driving performance and to develop a first version of a biomathematical model of fatigue that takes next-day effects of alcohol into account. The study is performed in a driving simulator and driver impairment is manipulated by experimenter-controlled administration of alcohol (target 0.05%). The study has a within-subject mixed-model design with a factor for next-day effects (driving with alcohol intake the day before versus driving without alcohol the day before) and a factor for time (in the morning and in the forenoon the day after). The experiment is carried out with 30 drivers who visit the lab three times, always in the same order.

1. Evening visit, 2 drives; one training drive and one drunk driving
2. Morning visit the day after the first visit, 2 drives
3. Morning visit without alcohol in the evening (baseline), 2 drives

Each drive in the car simulator includes 25 min rural road and 10 min urban road. Sleep is tracked off-site by diaries and wearables. Subjective sleepiness, objective fatigue indicators, and simulator data is collected during the drive. BrAc, attention and stress level are measured before and after each drive.

9.1.2 UCB-S1

Fatigue, alcohol consumption and stress will be addressed in the UCB simulator pilots in Thessaloniki, Greece. 20 taxi drivers and 20 delivery service riders will participate in simulator tests in a car and PTW simulator. A repeated within-participants design is applied with baseline measurements collected at the first session. The drivers will participate in three counterbalanced sessions, one before their shift starts, one after their shift ends and one where they arrive at the middle of their shift. Fatigue is assumed to increase from the start of the shift to the end of the shift. Stress is manipulated through events in the simulator scenarios. Alcohol will be manipulated through experimenter-controlled administration with four target levels in three sessions (0, 0.02%, 0.05%, >.05%).

Fatigue will be measured before the session, after the session and continuously using KSS. Stress will be measured before and after the session, and continuously during the drive through Galvanic Skin Response (GSR). BrAc will be measured before and after each drive. Fatigue and stress scales will be administered before and after the session and stress will also be measured after events. Each impairment state is measured by the PANACEA technologies and a reference technology.

Table 8. *UCB – S1 design and procedure*

Part of session	Time
Informed consent	-20 mins
Briefing and ethical rights	-5 mins
BASELINE & pre-shift (1st session)	**0 mins**
Pre-questionnaire completion on fatigue, stress and alcohol use.	10 mins
Driving/ Riding simulator familiarisation	5 mins (only during their first session; sessions will be counterbalanced)
Fatigue, stress, alcohol baseline measurements (this includes 0% level alcohol) are taken.	30 mins (including 10 mins setting up and measurement collection) and collection with both reference and PANACEA technologies and 20 mins driving/ riding simulator.
Alcohol consumption (0.02%)	20 mins
Post questionnaire completion on fatigue, stress and alcohol state. Incl. some question items on the technologies (in the first session).	15 mins
Checking data collection status and quality	5 mins (in parallel with debriefing)
Debriefing	5 mins
During Driving/ Riding (2nd session)	**0 mins**
Pre-questionnaire completion on fatigue, stress.	10 mins
Driving/ Riding simulator familiarisation	5 mins

Part of session	Time
Simulator fatigue driving/ riding scenario	20 mins
Post question completion on fatigue, stress	10 mins
Simulator stress driving/ riding scenario	20 mins
Post question completion on fatigue, stress	20 mins
Debriefing	5 mins
Post- shift (3rd session)	**0 mins**
Pre-questionnaire completion on fatigue, stress and alcohol	10 mins
Driving/ Riding simulator familiarisation	5 mins
Simulator fatigue driving/ riding scenario	15 mins
Post question completion on fatigue, stress and alcohol	10 mins
Simulator stress driving/ riding scenario	15 mins
Post question completion on fatigue, stress	10 mins
Simulator alcohol (>0.05%) driving/ riding scenario	20 mins
Post questionnaire completion on fatigue, stress and alcohol	10 mins
Checking data collection status and quality	5 mins (in parallel with debriefing)
Debriefing	5 mins

9.1.3 UCB-S2

The study will be realised as permutated within-subjects design with two independent variables: (1) the *kind of driving environment*: city vs. highway, and (2) *kind of driver distraction*: no distraction vs. cognitive vs. visual/manual vs. cognitive/visual. The different kinds of driver distraction will be induced by different secondary tasks that the driver needs to perform in permutated order during the drive.

As dependent variables, different parameters will be measured to capture the behaviour and state of a driver (see Figure 10 for an overview). Primarily, the focus will be on parameters capturing gazing behaviour (e.g., temporal gaze variance, gaze off road), driving behaviour (e.g., steering wheel angle, SD headway, whether the hand(s) are on/off the steering wheel, stress, and cognitive load. In addition, subjective measures such as perceived distraction,acute stress (VSS), and sleepiness (KSS) will be captured after each drive, and measurements with the SmartPWA device will be conducted at defined points in time during the experiment At the end, a half-structured interview will be conducted with participants on tactical and operational countermeasures for distraction.

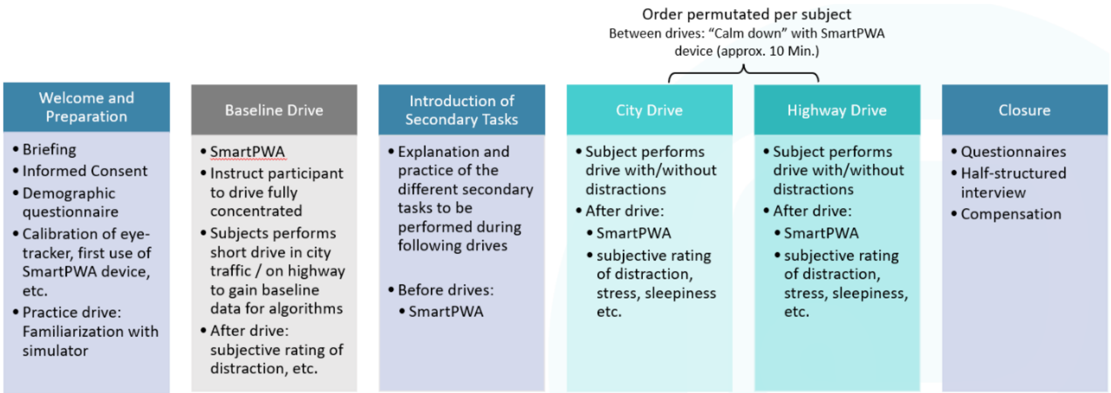

Figure 10. *Planned study procedure for the VIF simulator study*

9.1.4 Roadside

The roadside assessments for validation of the PANACEA roadside sensors will be performed in two separate data collections, one for the validation of the Senseair Go portable alcohol sensor and one for the validation of the Leitat biosensor. Testing will be done according to the regular operations of the traffic police in Norway, only adding the PANACEA sensors as an additional step in the testing procedure. Additional testing with PANACEA sensors will be optional for the drivers being stopped at the roadside. The roadside study for alcohol will primarily test among ordinary public road-users, with a planned target of 600 tests with at least 31 positive tests. The procedure for alcohol testing is shown in Figure 11.

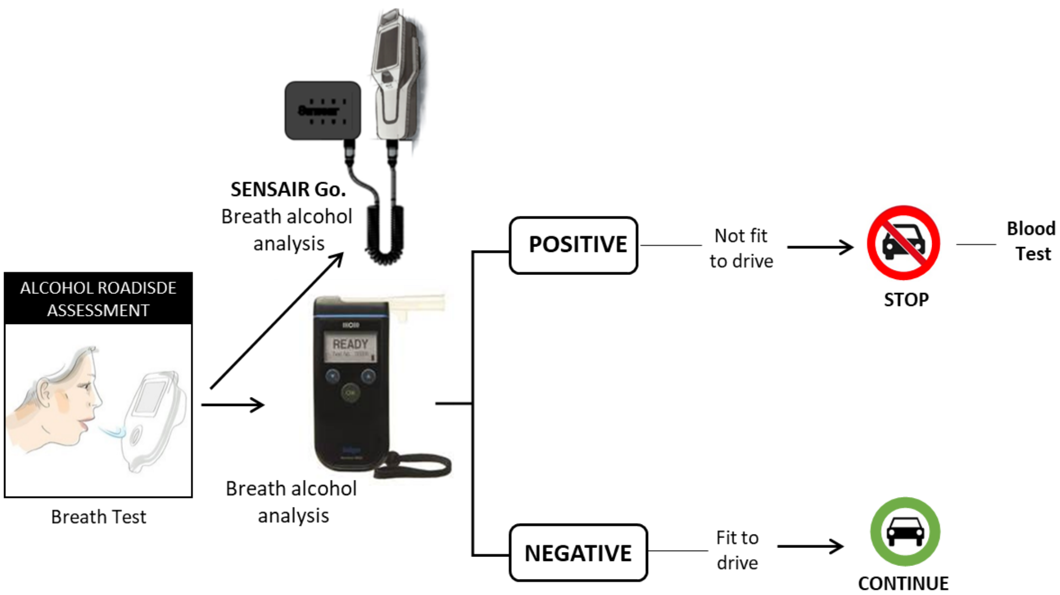

Figure 11. *Alcohol testing in the roadside study.*

Drug testing will follow a different approach, as described in Figure 12, since there is a greater need to check for false positive and false negative tests. The roadside study for drug will aim for a minimum of 100 samples, including both positive and negative results. With a target of reaching 11 positive tests for Benzodiazepines.

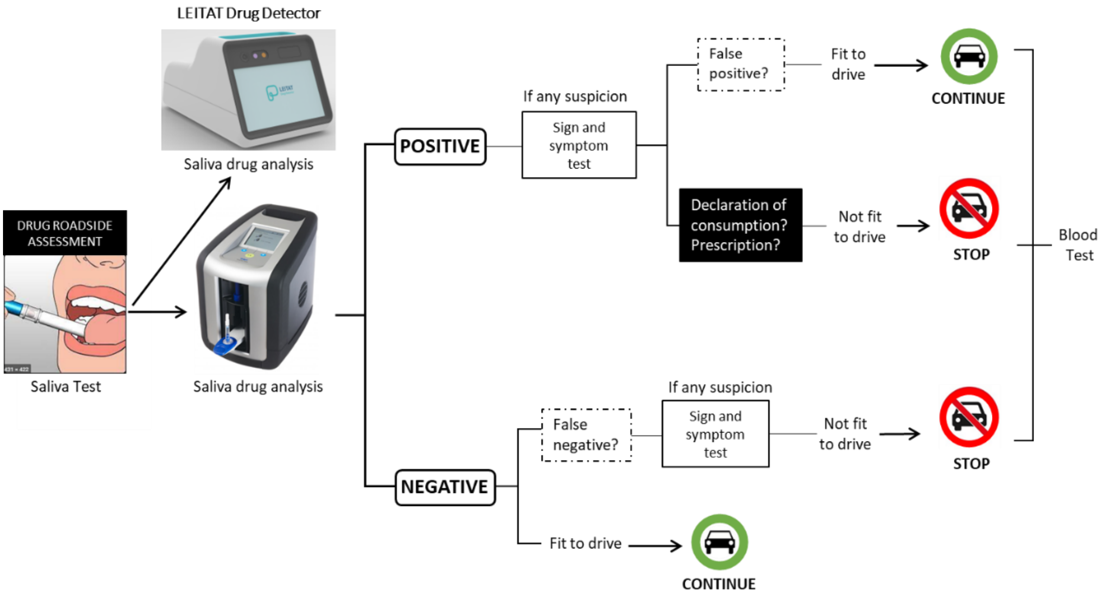

Figure 12. *Procedure for drug testing in Norway.*

9.2 Validation and assessment pilots (A6.3) and countermeasures' pilots (A6.4)

The real-world and semi-real-world studies UCA-R, UCB-R and UCC-R have the combined purpose of collecting data for validation and assessment of the CHTs (A6.3) and for evaluation of the countermeasures (A6.4). The CHTs' assessment pilots are based on a repeated measures design where the PANACEA solution will be evaluated on repeated occasions (at least 3 repetitions per CHT). This is part of the iterative process, serving the feedback loop to WP4 and WP5. The procedure for sharing the main outcomes or needs for improvements with WP4 and WP5 is described in chapter 14.1 Data delivery. The short-term and immediate countermeasures will be evaluated in the pilots running in parallel with the A6.3 studies. The evaluation of longer-term countermeasures and training content will be performed in dedicated focus groups (at least two per pilot site) with both drivers (or riders) and operators. The data collected will be fed back to WP5, to further improve the system.

9.2.1 UCA-R

In UCA, data collections will be done during the normal operation of the autonomous shuttles in Linköping with 8 safety drivers participating. A within-subjects design will be used with before and after measurements. Data collections will be done continuously for two 1-month periods, ensuring that all safety drivers will use the PANACEA solution during several work shifts. A baseline assessment will also be done in the beginning of 2023 with "passive sensors", ideally collecting data with Senseair, AIT smart PWA, Fitbit and Datik but without countermeasures or other feedback to the drivers. During the baseline assessment, the PANACEA platform will not provide feedback to drivers and operators. The data collection for final evaluation with the full PANACEA solution activated, including the countermeasures system, will be performed for one month in April 2023.

9.2.2 UCB-S3 and R

40 drivers and riders will participate in the semi-real life evaluation phase. Fatigue, stress, and distraction will be evaluated in the simulator and fatigue only with the instrumented vehicles (shown in Figure 5). For ethical and legal reasons, alcohol, and drug replacement therapy (i.e., will be tested in the passenger car and motorcycle simulators (Figure 3). The design and procedure of the tests will be like the one for the simulator tests (see Table 8) with participants arriving to participate in three counterbalanced sessions. Separate procedures have been prepared for the simulator studies, the semi-real-life tests, and the drug replacement study. They are presented in the UCB Experimental plan (Annex II).

Alcohol will be administered to the four levels, as in the simulator studies. Similarly, methadone will be administered at the affiliated rehabilitation clinic and participants will arrive 8 hours after they received their prescribed dose. A health care professional will always be present during testing when alcohol and drugs are administered. Ethical approval will be obtained prior any testing takes place. Data collection will be conducted between May and July 2023.

9.2.3 UCC-R

The study design will be the same for all three driver groups (R1-garbage truck drivers, R2-interurban bus drivers, and R3-long distance bus drivers). Approximately a total of 15-20 drivers will participate, counting the 3 demonstrators and sites. Data collections will be done during the normal operation of the garbage trucks and bus services. The period for testing will be 3 months, including 1-month baseline with “passive” sensors and 2 months with the full PANACEA solution, i.e., with all sensors and displays and countermeasures.

10 Data gathering tools

Several different types of data gathering tools will be used in the project. They include both subjective and objective tools to make sure the individual studies can answer their specific research questions and to provide good quality data for the impact assessment.

10.1 Objective data

The PANACEA sensors and technologies will be the main data gathering tools providing objective measurements of driver impairments in all data collections. Detailed descriptions of the technologies and their respective output parameters can be found in deliverable D3.1: 'Methodologies for a holistic fitness to drive assessment'. Instructions on how to carry out measurements off-duty, on-duty, on-site and roadside are available to the pilot sites in the internal deliverables ID 3.1: 'Off-duty assessment: Measures and Thresholds' ID3.2: 'On-duty assessment: Measures and Thresholds', ID3.3: 'On-site assessment: Measures and Thresholds', and ID3.4: 'Roadside assessment: Measures and Thresholds'. The terms off-duty, on-duty, and on-site describe the different work shift phases for professional drivers and these terms are relevant for the final evaluation of the PANACEA solution in the operational setting. For the simulator studies, these correspond to measurements taken off-site, during driving, and on-site. Below is an overview of PANACEA technologies used as data gathering tools per work shift phase and study.

Table 9. *Objective data collection tools used in the various work shift phases in the studies. DDA=during driving assessment (UCS14), ODA=off duty assessment (UCS16), ONPDA=on site & pre-driving assessment (UCS13), RSA=roadside assessment (UCS15).*

Sensor or technology	Output	ODA	ONPDA	DDA	RSA
DATIK FitDrive (UCS01)	Fatigue level, detected events			UCA-R, UCB-S1, UCB-S3 and R, UCC-R	
DATIK pre-questionnaire (UCS01)	Fatigue risk level		UCA-R, UCB-S1, UCB-S3 and R, UCC-R		
Senseair Go (UCS02)	Breath alcohol content (BrAc)			UCB-S1, UCB-S3, UCC-R	
Senseair Go Portable (UCS02)	Breath alcohol content (BrAc)				Roadside

Sensor or technology	Output	ODA	ONPDA	DDA	RSA
Senseair Wall (UCS02)	Breath alcohol content (BrAc)		UCA-R, UCB-S1, UCB-S3, UCC-R		
Leitat biosensor (UCS03)	Benzodiazepines and methadone concentration in saliva		UCA-R, UCB-S3, UCC-R		Roadside
AIT Smart PWA (UCS04)	Stress, fatigue, and cognitive load	UCB-R, UCC-R	UCA-S, UCA-R, UCB-S2	UCB-S3, UCC-R	
ViF Driver Monitoring System (UCS05)	Cognitive distraction			UCB-S3, UCC-R	
DBL Neuromatics Toolbox (UCS06)	Cognitive load and Stress		UCB-S2	UCB-S2	
BACtrack Skyn (UCS07)	Transdermal Alcohol Content (TAC)	UCB-R,	UCB-S1, UCB-R	UCB-S1, UCB-S3 and R	
Fitbit (UCS08)	Activity, sleep/wake patterns and sleep stages	UCA-S, UCA-R	UCA-R	UCA-R	
BMM (UCS09)	Fatigue level	UCA-R	UCA-R	UCA-R	
Optalert (UCS10)	Fatigue level			UCB-S1 and S3	
GSR (UCS10)	Arousal (Skin conductance)			UCB-S1 and S3	

10.1.1 Output from PANACEA solution/platform

In addition to the measurements obtained from the various PANACEA sensors, the integrated PANACEA solution will enable collection of data regarding usage, impairment levels, triggered warnings, delivered countermeasures, statistics/ analytics (through dedicated dashboard) and engagement with the countermeasures' system. A preliminary data clustering was enclosed in D9.4 'Data Management Plan' (M6). The complete list of data types and characteristics along with any restrictions, embargo periods and open sharing possibilities will be annexed in D9.5 'Data Management Plan – an update' (M34). Likewise, the data available from the technologies, along with the agreed upon thresholds will be available in D3.1 'Methodologies for a holistic fitness to drive assessment' (M16) and the final decisions based on the A6.2 outcomes and PANACEA solution prototype will be included in D3.2 'Methodologies for a holistic fitness to drive assessment - an update' (M24).

10.1.2 Reference sensors

In the simulator and roadside studies, reference sensors will be used to enable validation of individual PANACEA technologies in relevant contexts.

Reference sensors in UCA-S are Smart Eye Pro which is a 4-camera remote eye tracking system and Vitaport 3 that measures Electrocardiography (ECG) and vertical Electrooculography (EOG) continuously during the drive. Both reference equipments enable measurement of fatigue/sleepiness indicators. A Dräger 6820 breathalyzer will be used to measure BrAc. In addition, a Psychomotor Vigilance Task will be used as a measure of alertness.

UCB-S1 will use reference technologies for fatigue via measurements of Electroencephalography (EEG) and ECG, for stress via measurement of ECG and for BrAc using a breathalyzer (standard equipment used by the police force).

In the UCB-S2 study, a SmartEye eye-tracking system will be used as a reference equipment for cognitive distraction using the parameters temporal gaze variance, gaze off road (AttenD), gaze variance on road, blink-rate, and fixation duration.

The roadside study will use a Dräger 6820 and 6810 breathalyzers as the reference equipment for BrAc and a Dräger DrugTest5000 for benzodiazepines and methadone or Securetec´s WipeAlyser in combination with DrugWipe® for benzodiazepines. Drug testing in blood samples will be done according to regular procedures used by the police force in Norway.

10.1.3 Vehicle data

To enable evaluation of the effectiveness of countermeasures and driver impairments on driving performance, vehicle and simulator data will be collected. In the UCA-S study, simulator data will be logged continuously during the drive including speed and speed variability, lane position and steering, surrounding traffic, including time headway and time to collision. In UCB-S1a data will be logged in the driving/ riding simulators about steering wheel angle, speed, lane position and headway variability along with braking activation and number of events. The UCB-S2 study will log Steering Wheel Angle, SD Headway, SD Lateral Position, and SD Speed from the driving simulator. A camera will also be installed to assess hand off wheel.

In UCA-R, shuttle data will be logged including: % automation activated, % hard brakings/ jerk, number of other road user interactions, number of passengers. For UCB-R both the simulators and instrumented vehicles will be used. Data logged will be the same as in the simulator study. In the instrumented vehicle, the data will be collected through the CANbus. UCC-R will log vehicle data including speed, acceleration, and lane position through the CANbus of the buses and garbage trucks. Parameters such as speeding, high RPM, harsh braking, excessive idle, and harsh acceleration are generated from the vehicle data.

10.2 Subjective data

Self-reported measures like questionnaires, rating scales, and focus groups will be used in the evaluation of the PANACEA system. A user profile will be included in the PANACEA solution with basic information about each driver or operator. The collected information will be the same for all final evaluation studies (A6.3 and A6.4). The user profile includes information about year of birth, gender, height, weight, and number of years as a professional driver. Additional information like medical conditions, lifestyle choices, etc. could also be included, but it was decided that the additional information will not be added in PANACEA A first version of the driver profile was described in Appendix IV of deliverable D1.1: ‘Use Cases’. Common before (background) and after (evaluation) questionnaires will be used in the final evaluations. The drivers will also complete a brief daily evaluation at the end of their work shift. All questionnaires can be found in Appendix IV. In addition, the countermeasure system has built-in evaluation questions as described in D5.1: ‘Countermeasures for drivers, operators, and enforcement. Content of the cloud-based coaching and support system’. These are for example quick evaluation questions like *Was this useful?* that are completed by the user after receiving a countermeasure.

10.2.1 Questionnaires

Questionnaires will be used to capture both background data of the participants (e.g., demographics) in each data collection, to track subjective experiences of the various driver impairments, and to evaluate acceptance, trust, usability, quality of life and other measures needed for evaluation and impact assessment. When available, validated questionnaire instruments will be used.

In the simulator studies, study specific background questionnaires will be used, comprising questions of relevance for the data collection. These include demographics, questions about the impairment states targeted in the study and other questions of relevance for the data analysis. During the trials, questions about impairment level (acute stress, sleepiness, intoxication etc.) will be used to follow the development of driver state over time. Self-assessments of driving quality will also be included in UCA-S1 and UCB-S1 trials. The roadside study will have a questionnaire to the police officers asking about the efficiency and usefulness of the PANACEA sensors for roadside assessment and brief questions to drivers about their experience of using the PANACEA sensors.

The questionnaires used in the final real-world and semi-real-world evaluations are the same across studies to enable comparisons between sites and to provide harmonised data for the impact assessment. The full before and after questionnaires will be completed by the professional drivers participating in the trials whereas a subset of questions will be completed by operators/managers. Additional questions can be added by the sites depending on the specific research questions addressed in the UC. The common before questionnaire includes the EQ-5D instrument for assessment of Quality-of-Life (QoL), the Alcohol Use Disorders Identification Test (AUDIT), the Epworth Sleepiness Scale (ESS), and questions about drug use, stress symptoms, and risky driver behaviors (including distraction). In the evaluation questionnaire, instruments needed for assessment of acceptance, trust, usability, safety, and willingness to have the PANACEA solution are included. The evaluation questionnaire comprises the same questions as the background questionnaire to enable before-after-comparisons. It also includes the Technology Acceptance Questionnaire (TAQ), System Usability Scale (SUS), SHAPE Automation Trust Index (SATI), and questions about willingness to have/use/buy and perceived safety. To evaluate the countermeasure system, specific questions about the strategic, tactical, and operational countermeasures are included. An overview of questionnaire instruments per study is shown in Table 10. The suggested questionnaire tools are included in Appendix IV. They were selected because they are well-established, validated across different EU countries and commonly used in transportation research.

Table 10. *Questionnaire instruments.*

Measure	Name of instrument	Output	Reference	Administration	Study
Sleepiness	Karolinska sleepiness scale (KSS)	Sleepiness score between 1 and 9	(Åkerstedt, Anund, Axelsson, & Kecklund, 2014)	Daily evaluation ONPDA, Repeated measures in simulator studies DDA, ODA, ONPDA	UCA-S, UCA-R, UCB-S1, UCB-S2, UCB-R, UCC-R
Daytime sleepiness	Epworth Sleepiness Scale (ESS)	Total score between 0 and 24	(Johns, 1991)	Background questionnaire	UCA-S, UCB-S1
Driving related sleepiness	Bordeaux Sleepiness Scale (BOSS)	Total score between 0 and 8	(Philip et al., 2023)	Baseline & evaluation questionnaire	UCA-R, UCB-R, UCC-R
Sleep problems	Karolinska Sleep Questionnaire (KSQ)	Selected items are included	(Nordin, Åkerstedt, & Nordin, 2013)	Baseline & evaluation questionnaire	UCA-S, UCA-R, UCB-S1, UCB-R, UCC-R
Acute stress	VTI acute stress scale (VSS)	Stress score between 1 and 9	Not validated	Daily evaluation ONPDA, Repeated measures in simulator studies DDA, ODA, ONPDA	UCA-S, UCA-R, UCB-S1, UCB-S2, UCB-R, UCC-R
Stress symptoms	Perceived stress	Single item question on 5-point Likert scale	(Elo, Leppänen, & Jahkola, 2003)	Baseline & evaluation questionnaire	UCA-R, UCB-R, UCC-R

Measure	Name of instrument	Output	Reference	Administration	Study
Alcohol use	Alcohol Use Disorders Identification Test (AUDIT)	Score from 0 to 40	(Babor, Biddle-Higgins, Saunders, & Monteiro, 2001)	Baseline & evaluation questionnaire	UCA-S, UCA-R, UCB-R, UCC-R
Drug use				Baseline & evaluation questionnaire	UCA-R, UCB-R, UCC-R
Risky behaviours (including distraction)	Self-declared behaviour from ESRA questionnaire	Selected items on 5-point Likert scale	(Meesmann, Torfs, & Van den Berghe, 2019)	Baseline & evaluation questionnaire	UCA-R, UCB-R, UCC-R
Acceptance	Technology Acceptance Questionnaire (TAQ)	Usefulness and satisfying scores ranging from -2 to +2	(Van Der Laan, Heino, & De Waard, 1997)	Evaluation questionnaire (focus on CHTs and countermeasures separately)	UCA-R, UCB-R, UCC-R
Usability	System Usability Scale (SUS)	Usability score from 0 to 100	(Brooke, 1996)	Evaluation questionnaire	UCA-R, UCB-R, UCC-R
Trust	SHAPE Automation Trust Index (SATI)	Mean score from 0 to 6	(Dehn, 2008)	Evaluation questionnaire	UCA-R, UCB-R, UCC-R, Roadside
Quality of life	EQ-5D	EQ-5D index, EQ-5D VAS score from 0 to 100	(Balestroni & Bertolotti, 2015)	Baseline & evaluation questionnaire	UCA-R, UCB-R, UCC-R

The drivers will also rate their level of impairment repeatedly during the test days to be able to follow the development of e.g., stress and sleepiness over time. Sleepiness will be measured with the Karolinska sleepiness scale (KSS), and stress with the VTI acute stress scale (VSS) as indicated in Table 10. When applicable, intoxication will be measured using the question *How intoxicated do you feel?* (0: completely sober; 10 very affected). In addition, to be able to track behavior related to the various driver impairments, drivers participating in the real-world studies will also complete daily evaluations to track sleep, stress, alcohol and drug use. The daily evaluation also includes brief questions about how well the PANACEA solution worked during the shift. The daily evaluation questions can be found in Appendix IV.

Simulator studies UCA-S and UCB-S2 will also have self-assessments of driving quality before and after each drive in the simulators. The questions asked are *How well do you think you will* *drive?* (0: worst imaginable; 10 best imaginable), and *How well did you drive?* (0: worst imaginable; 10 best imaginable).

10.2.2 Focus groups

Focus groups with stakeholders will be performed in all final evaluation studies. The evaluation of the countermeasures and training content will be performed in dedicated focus groups (at least two per pilot site) with drivers (or riders) and operators and enforcement officers (if possible). The aim will be to conduct at least two focus groups per pilot site, but interviews may be used to capture operator feedback if appropriate. The data collected will be fed back to WP5, to further improve the system.

11 Data analysis plan

The UC teams are responsible for creating a data analysis plan for each data collection based on the study design and connected research questions. Repetitive data treatment will ensure collection of adequate volume and to reach the set KPIs and answer the research questions. After each repetition, data will be used to improve the technologies and their integration to CHTs (WP4) and resolve any technology issues. The general data analysis plan for simulator, roadside, and real-life studies has its starting point in the high-level research questions (Table 11).

Table 11. *General data analysis plan.*

High-level RQ	Analysis plan
Do the relevant PANACEA sensors/systems detect targeted driver impairments effectively with high sensitivity and specificity?	Measure the number of correctly classified driver impairments according to the thresholds defined in WP3 when driver impairment level is known (by manipulation of driver state or via gold standard reference measurement of driver state).
How is the performance of the PANACEA sensors compared to a reference measurement?	Analysis of correlation between PANACEA sensor and reference sensor. Compare number of correctly classified driver impairments between PANACEA sensor and reference sensor.
Do the combined sensors improve driver state detection?	Compare number of correctly classified driver impairments between individual PANACEA sensors and combined sensors.
Does the PANACEA integrated solution work in a real-life setting to detect impairment and deliver countermeasures?	Analyse number of correctly classified driver impairments in real-life settings (compare with subjective rating of impairment) Analyse usage data from PANACEA solution.
Are the PANACEA sensors/systems accepted by the users?	Calculate scores for acceptance from questionnaires and compare with cut-offs or normal ranges for each instrument
Are the CHTs perceived as useful, satisfying, trustworthy, and easy to use?	Calculate scores for usability, satisfaction and ease-of-use from questionnaires and compare with cut-offs or normal ranges for each instrument
What are the immediate effects of implemented countermeasures?	Analyse difference in driver impairment level before and after receiving a countermeasure.

High-level RQ	Analysis plan
Is the PANACEA countermeasures system accepted by the users?	Calculate scores for acceptance from questionnaires and compare with cut-offs or normal ranges for each instrument
Does behaviour change/improve after the relevant countermeasure has been administered?	Compare sleep habits, stress level, alcohol and drug use before and after receiving countermeasures.
Will the PANACEA countermeasures reduce driver impairment and improve the driver performance?	Analyse changes in driver impairment level and driving performance over time when the PANACEA solution is used.
Would it be possible to implement the PANACEA system in regular operation?	Analyse output from focus groups with stakeholders after they have experienced the PANACEA solution.
Does the PANACEA system increase perceived (drivers) and reported (operators) safety?	Analyse changes in driver impairment level and driving performance over time when the PANACEA solution is used. Analyse results from questionnaire about safety.

The UC teams should take potential risks of bias and threats to validity into consideration in the data analysis plan. This can be done by identifying potential confounding factors, risk of bias, and other interfering effects beforehand. Examples are carry-over effects, learning effects, drop-outs, timing of tests, incentives, and experimenter bias. These can be handled either by employing a study design that balances out potential risks of bias or by measuring these factors to be able to control for them in the statistical analyses.

12 Pilot site preparations

The teams located at the pilot sites will refine and operationalise the procedures as defined within A6.1. Each UC team is also responsible for obtaining Ethics approval, if needed, prior to any testing. For the studies to be conducted smoothly and without delays, preparations will go beyond what is described in this deliverable. Apart from the necessary technical equipment, the following aspects will be considered while preparing the data collections, if applicable to the study.

12.1 Ethics

PANACEA is a complex project with ethical issues related to security, privacy, and interoperability. Each phase of the project will be addressed accordingly from the project concept development to the project closure.

Core ethical issues within PANACEA are related to:

- Data privacy protection, confidentiality, and transparency
- Informed consent
- Incidental findings
- Transparency of the collected data management by the PANACEA solution and during its WP6 pilots
- IT-Security and identity management
- Risk assessment (Insurance)
- Delegation of control
- Incentives (financial inducements, compensations, etc.)

Local Ethics Representatives will be the main contact point for any ethics related issues (e.g., submission of research/test protocols for approval by the Institutional/National Ethics Committees, GDPR issues, etc.) from the pilot site point of view. The Ethics Management Panel will tackle user involvement and ethical and data protection issues. In addition, one of the main tasks of the nominated persons will be to co-ordinate and be responsible for obtaining approval by the local/regional/institutional ethics committee before any pilot related activities take place (e.g., even before recruitment starts) - if needed. On the other hand, the Ethics Board (EB) will scrutinise the research, to guarantee that no undue risk for the user, whether technically or related to the breach of privacy, is possible.

As evaluations will take place in four countries across Europe, attention should be specifically paid to the (relevant) national/regional/institutional regulation of each country. To collect national regulation and local ethics practices, a questionnaire has been formulated and provided in Annex I and the results of which are reported in chapter 4 of D9.2.

An Ethics Site Responsible has been chosen for each Use Case (local ethics representative), who represents the country with respect to ethics issues in specific. EB will train and monitor the Local Ethics Representatives to abide to the European and national regulation, laws, and guidelines and PANACEA Ethics Policy. In turn, the ethics responsible person at each pilot site will train and appoint the person who will be managing and organising recruitment processes and safekeeping of participants contact details. The ethics responsible person will inform the

EB of any recruitment issues and threats that may appear with regards to data protection and end-user involvement in pilots.

Training delivery (face to face, online remote, documentation sharing, etc.) to the local ethics representatives will be managed case-by-case.

PANACEA Ethics Board will also be closely collaborating with the WP6 pilot leader who will act as the moderator and communicator between the pilot sites and the project's EB team. All Ethics approval will reside on SharePoint and will be annexed in the next version of the Ethics deliverables' series (D9.3; M22).

12.2 Data protection

For PANACEA to achieve its mission and to meet its objectives, a series of data, including personal data, is required to be collected, processed, used, and managed. Data collection and processing in PANACEA adheres to the respective European regulations, encompassing General Data Privacy Regulation (GDPR) and the PANACEA Data Management Plan (D9.4; M6 and D9.7; M34). Pilot site leaders will complete a Data Protection Impact Assessment (DPIA; Annex VII in D9.4) necessity form to investigate if a DPIA needs to be initialised beforehand. This process started in M15 and will be completed before any tests take place. In addition, pilot representatives will participate in the completion of the FAIR templates (section 5.3 and Annex VI in D9.4) to identify the data characteristics, restrictions, etc. If data exchange requires an agreement, this will be prepared accordingly.

12.3 Covid-19 measures

Considering the Covid-19 pandemic, each UC team is also responsible for taking necessary measures to ensure minimal risk of spreading the SARS-CoV-2 virus. These could include the use of personal protective equipment, intensified cleaning of vehicles and facilities, measures to avoid crowding, or modified data collection procedures depending on the situation at the time of data collection in each study. The pilot sites are responsible for adhering to local Covid-19 restrictions during data collection activities. Adaptations should be clearly described in the internal reports from each study.

12.4 Technical validation

The aim of the technical validation is to check the technical functioning of the PANACEA data collection systems in the real operational (or simulator) setting. It will enable identification of potential problems with the sensors and should also permit to validate the data collection procedure from data acquisition and data transmission to data storage. The iterative process will ensure that any problems encountered during implementation can be fed back to relevant WPs and be resolved before starting the main data collections.

The technical validation must be prepared and conducted prior to the visit of the first participant. The technical validation can be performed with a member of the working group that is not directly involved in the preparation of the study. This will assure a higher independency of the feedback given regarding failures and improvements. The technical validation should be conducted exactly as if it was a session with a real participant (information sheets, technical protocol, experimenter guide and instructions should be used). This serves to verify if all equipment is working properly and if the procedure is efficient. During the technical validation, data must be recorded as this allows to confirm if the output dataset can be used to perform the planned analysis.

Protocols for technical validation will be developed in A6.2, A6.3 and A6.4 in collaboration with WP4. The results of the technical validations will be reported in MS15-MS17. The protocol for A6.2 can be found in Appendix I.

13 Data collection

This section presents an overview of what the steps that will take place at the sites during data collection.

13.1 Participant recruitment

When recruiting participants to the studies, selection criteria will be considered such as gender, and age. Care should be taken to ensure a representative sample, and a sufficient sample size. The recruitment will be done before the data collection takes place in all studies except the roadside study and will be conducted by the respective team on site. All people that will be actively participating in a study, will take part in a thorough recruitment and informed consent procedure, that will be particularly stringent to ensure no coercion (not even soft or indirect) is exerted. In the Ethics manual of PANACEA, the recruitment process is described and information to be included in the recruitment material is listed. The study can be advertised in the media (e.g., website, local newspapers, email messages), locally (distribution of prospects and information sheets in the facilities), and via direct contact of potential participants. Some extra participants should also be recruited in case of drop-out. Appointments will be scheduled with the participants and, to assure that drivers do not forget an appointment, a member of the pilot team will call the driver/operator/passenger a day before reminding him/her about the scheduled session's time.

13.2 Information sheets, consent forms and questionnaires

The informed consent procedure is described in detail in the Ethics manual of PANACEA. Each UC team will edit the required templates of the informed consent and information sheets and will define the procedures regarding the collection, storage, and protection of personal data, in compliance with the European and national legislation. The Pilot sites are responsible for translating all the material that need to be read or filled out by participants if the participants do not have enough English skills. Consent forms need to be signed before the data collection starts and should follow the requirements specified in the Ethics manual of PANACEA. Questionnaires and scales will be implemented in web-based applications, which will ease storing information and reduce the amount of work prior to data analysis. A common web tool will be used at all final evaluation sites to facilitate comparison between sites.

13.3 Protocols and instructions

It is recommended to create a study protocol consisting of a checklist for each data collection to ensure that all equipment is in place and working. It facilitates reviewing that all sensors and vehicles/simulators are working as intended before the data collection starts. Before starting the data collection, members of the staff should go through this protocol. A schedule of the study should be attached to the protocol. The schedule should contain a list of all participants with a time plan for when each participant is scheduled for data collections.

The protocol should also show, step by step, which actions the experimenter from the UC team should take to set up and run the study, including which materials are needed, where he/she should ask the participant to do, and instructions that must be given to the participant. Certain information, like goals of the study, test procedure and system description, must be read (verbally) in order to assure that all participants receive the same instructions.

13.4 Procedure

The procedure for collecting data using the PANACEA sensors is described in detail and available to the pilot sited in the internal deliverables ID 3.1: 'Off-duty assessment: Measures and Thresholds' ID3.2: 'On-duty assessment: Measures and Thresholds', ID3.3: 'On-site assessment: Measures and Thresholds', and ID3.4: 'Roadside assessment: Measures and Thresholds'. Baseline measurements in the final evaluations should be taken using the applicable PANACEA sensors "passively", i.e., without having the connected countermeasures' system activated. For reference measurements, the pilot sites are referred to the respective technology's user manual.

14 Data analysis and reporting

14.1 Data delivery

All raw data collected will be transferred to PANACEA platform automatically, fetched by PANACEA platform at regular interval(s), or deposited in PANACEA data storage at certain delivery times.

For the data to be deposited, all datasets will be placed at a designated folder in SharePoint. The data will be accompanied with a "cover sheet" (Appendix V) that describes the data. Data must already be anonymized before being placed in the designated folder. The data upload and the cover sheet must be checked and approved by the data owner. The cover sheet is taken from Table 2 of PANACEA D9.4.

Derived/processed data that are made at the different analysis stages at the sites will also be shared for consolidation analysis.

14.2 Data analysis

Each UC team will be responsible for collecting and pre-processing and/ or processing datasets according to the data analysis plan. Most of the pre-processing is done by the UC teams at the pilot sites. Data analyses will be performed both centrally and at the sites, depending on the purpose of the data analysis. A6.2, A6.3, and A6.4 will do some analyses related to their respective activities. The analysis in A6.4 will: a) answer the research questions and address the evaluation-oriented objectives as described in this deliverable, and b) assess acceptance, trust, willingness to use of drivers/riders/operators and stakeholders of CHTs, countermeasures and of the PANACEA solution in general. WP3 will use the data delivered by A6.2 for final setting/ refining of thresholds, levels and algorithms. Some analyses will also be performed in A6.5 with the purpose of consolidating findings from the different pilot sites and seeing the research questions cross-pilot sites (not per pilot site). Impact analysis and calculation of high-level KPIs is done in WP7.

Some steps of the data analysis are common for all studies. The first step is to perform a data quality check. This should preferably be performed at regular intervals also during the data collection to see if any problems arise over time. Thereafter, cleaning and pre-processing of data will be done by removing bad quality data and calculating output parameters. In this step, it is important to register how much of the data was removed due to bad quality. For the PANACEA technologies the output parameters will be calculated by the PANACEA system, but for the reference equipment used in the simulator studies the data processing will be done by the respective pilot site. Data from questionnaire instruments used in the evaluation will also be processed at the sites. This includes re-coding of individual ratings and calculation of scores and indices according to the description for each instrument. The final questionnaire tools and can be found in Appendix IV.

14.3 Reporting results

Results from each study will be compiled by each site and they will write internal reports based on pre-defined templates. The table of contents for the study reports can be found in Appendix VI). Each report will include a description of the research questions, methods, analysis, results and conclusions of each data collection. The structure of the internal report is similar to the experimental plan for the respective study but includes the analyses performed, results and conclusion sections. The consolidated results of all studies performed in WP6 will be reported in D6.3: 'Consolidation of Pilots' results' as described in the chapter below.

14.4 Results consolidation

Following the tests and analyses conducted in A6.2, A6.3 and A6.4, data and analysis results will be reported by these activities from all pilot sites. Such data and results will then be used in A6.5, further analysed, discussed, and made publicly available in D6.3 and/or journal/conference publications. Results (both raw and metadata based/consolidated) will be provided to WP7 for performing the impact assessments, as well as to A7.4 to adapt to the relevant exploitation plans. The conclusions are expected to lead to recommendations for future system(s) optimisation, application guidelines and areas requiring further research and lessons learnt.

15 Impact assessment

Impact assessment will be performed in WP7, starting in M22 of the project. The main aim is to assess the project impacts enabling and verifying the release of the impacts/benefits of the project. The specific aspects investigated are: the project impact in relation to the EU safety targets; the impacts of the countermeasures proposed and developed by the project (related to A6.3); cross-modal transferability, ensuring that the outputs of the project are beneficial also in other transport modes (related to A6.4); the simulation of various scenarios to explore the impacts of the project solutions at different levels. As illustrated in Figure 13, the PANACEA impact assessment process is highly dependent on data from the WP6 data collections as input to the various WP7 activities.

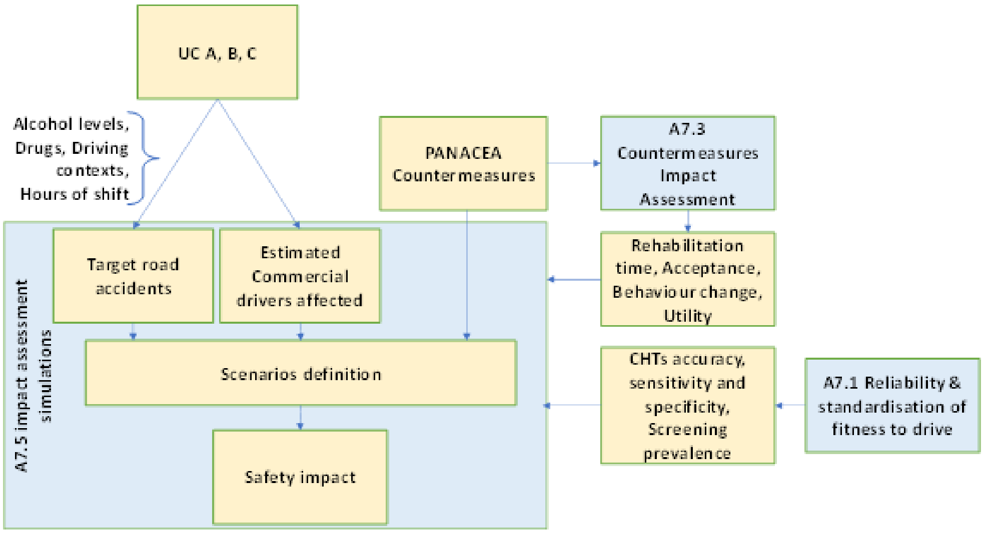

Figure 13. *The PANACEA impact assessment process*.

A7.3 aims to assess the impact of the countermeasures developed in WP5 and piloted in WP6 and to evaluate their potential impact in relation to the PANACEA impact targets beyond SoA. The results from the countermeasure pilots (simulator and on road/test track pilots and the cloud-based coaching and supporting system tests) will be used to assess the impact of these countermeasures. The impact of the pilots will be measured in terms of behaviour change, fit for purpose assessment and user acceptance. The potential impact of the countermeasures will be evaluated in terms of combating driving impaired by medicines or excess fatigue will be evaluated. A focus will be the extent to which they can accelerate rehabilitation (project target of 20%) and combat the appearance and perseverance of the addressed impairment types (project target 25%). The impact of the cloud-based coaching and supporting system on improving efficiency and effectiveness of roads policing/traffic police operations will also be assessed. This task is dependent on the work in WP5 to develop countermeasures and the design and running of the pilots in WP6.

Moreover, the EU Road Safety Policy Framework (2021-2030) has set a long-term, comprised by interim ones, goals to reach zero deaths and injuries by 2050 (addressed by A7.2). An analysis of the safety impact mechanisms of each UC will define the target road accidents and related road injuries addressed by each one of them. The AIT mobile unit, for example, can play an important role in the early detection of high and low arousal states Initially, the Fitness-to-Drive assessments are planned as on-the-spot measurements at pre-defined occasions (e.g., start of shift, in regulated breaks, etc.), which will return indicators for the arousal states to initiate preventive strategies. In the long term, an integration into the driving environment (e.g., steering wheel) is realistic to allow for a continuous assessment triggering the immediate initiation of needed preventive strategies. Commercial drivers are at high risk for crashes with severe impact on various social (e.g., injuries, deaths) and economic (e.g., consequential costs due to acute injuries, long-term health complications, environmental damages, traffic breakdown, delivery problems) levels. Thus, already a small reduction in crashes can lead to a significant reduction in fatal/non-fatal events and consequential costs. The AIT innovation might as well have an impact on the automotive industry by opening a new area of integrated and unobtrusive assessment of the driver's fitness even in the non-commercial driving business. Furthermore, the obtained findings can be translated to other domains (e.g., medical domain) and environments (e.g., sports) as well. Several scenarios will be built according to various input like the number of commercial drivers affected, the performance of CHTs and the countermeasures proposed in PANACEA. Each scenario will be compared to the reference scenario, which assumes no major improvements are implemented. The safety impact of the proposed solutions will be estimated based on results in terms of rehabilitation time, user acceptance, behaviour change and CHTs reliability and screening prevalence coming from activities **A7.1 and A7.3.**

16 Conclusions

This deliverable provides the framework for all WP6 data collections. In the updated version, final KPIs, detailed experimental plans, questionnaire tools, protocols for technical validation, and templates for data harmonisation have been added. The purpose of the PANACEA framework is to create a common framework to be used in all studies to make sure the data are collected in a way that makes it possible to consolidate the results in the end and to provide what is needed for impact analysis. Studies will be done to serve different purposes during the project. Simulator (A6.2) and roadside (A3.4) studies will be performed to validate PANACEA sensors and refine WP3 algorithms. Real-road and semi-real-road studies will be performed to validate and assess the final CHTs (A6.3) and countermeasure solution (A6.4).

The deliverable presents both a horizontal perspective of the pilot sites and what will be included in the different studies, but also the details for each site to be able to perform the data collections needed to for the generic evaluation and impact assessment. The general data gathering tools (objective and subjective) are identified and specified for each study. A set of guidelines on practicalities and ethical aspects to take into consideration before and during data collection are presented.

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Appendix I Technical validation protocol

Technical Validation Protocol for PANACEA simulator studies

The purpose of this document is (1) to gather structured information about the different simulator studies to be conducted in PANACEA in terms of technical validation, and (2) to support the study preparation and post-processing with check lists. The protocol consists of two parts: Part 1 needs to be filled in before study conduction, Part 2 after the study has been finished.

----------------------------------- **Part 1: Before Study Conduction** -------------------------------

General study information

Study name and ID (as defined in D6.1):

Leading partner:

Kind of simulator / kind of vehicle used for the study:

Targeted number and kind (e.g., taxi drivers) of participants:

Which PANACEA technologies are going to be used in the study?

☐ AIT Smart PWA	☐ VTI BMM
☐ Fitbit	☐ Senseair Go
☐ BACtrack Skyn	☐ Senseair Go Portable
☐ DBL Empathica EDA Wristband	☐ Senseair Wall
☐ DBL Mindtooth EEG Headset	☐ DATIK FitDrive
☐ Optalert Eagle LIGHT and Grove GSR	☐ DATIK Pre-questionnaire
☐ LEITAT Drug Detector	☐ VIF DMS

Which further non-PANACEA / reference sensors are going to be used in the study?

Which questionnaires are going to be used in the study?

Which additional data is captured in the study? (e.g., driving data, interview data, etc.)

Which data is going to be provided to WP3 / the technology providers? Who will be responsible for the data analysis?

Checklist for study preparation

	Check
Is the study design, the research questions, and procedure available in written form?	☐
Is the informed consent (information about study, captured data, data protection) for the participants prepared in written form?	☐
Has the study been ethically approved? Please provide the ethical approval number:	☐
Is the experimenter's guideline (detailed description of the study procedure for the experimenter including all participant instructions, technical to dos and procedures, which questionnaires to provide when, etc.) prepared in written form?	☐
Have all planned questionnaires correctly been setup according to the respective questionnaire guideline? ☐ no questionnaires planned	☐
Please indicate, which tools (e.g., LimeSurvey, Microsoft Forms) have been used to setup the questionnaires (if any):	
Please describe how data privacy is ensured (how is the data shared with the partners?):	

Please fill in for each <u>PANACEA sensor</u> you are going to use in the study:

Are you aware about the requirements/procedures for a proper functioning of the respective sensor in your setup? Has the installation of the respective sensor worked? Has it been setup and tested (i.e., does the respective sensor correctly capture and provide the data it's supposed to measure)?		**Check**
Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐
Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐
Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐
Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐

Please fill in for each <u>reference sensor</u> you are going to use in the study:

Are you aware about the requirements/procedures for a proper functioning of the respective sensor in your setup? Has the installation of the respective sensor worked? Has it been setup and tested (i.e., does the respective sensor correctly capture and provide the data it's supposed to measure)?	**Check**

Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐
Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐
Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐
Sensor name:	Requirements/procedures are known	☐
	Installation successful	☐
	Sensor works correctly	☐

Please describe briefly how the synchronization / connectivity of the different sensors is achieved:

Temporal event triggered, user profile, ID, etc.	
Are all sensors connected / synchronized according to the above description?	☐

Pilot test:

	Check
Have you performed a pilot test of the full setup (i.e., following the full experimenter's guideline) with at least 2 participants?	☐
Have you checked the recorded data of the pilot runs (i.e., has all data been recorded, has it been recorded as planned, did the synchronization work as planned)?	☐

Please briefly describe, whether and which changes of the setup were necessary after the pilot tests. If there are unresolvable issues, how are they going to be mitigated?

Based on the pilot tests, what is the expected study duration per participant:

------------------------------------ Part 2: After Study Conduction ---------------------------------

Study name and ID:

Leading partner:

Please indicate the total number of study participants

Please indicate the total number of valid data sets (i.e., number of participants, whose data will be used for data analysis)

Please provide the following information for each PANACEA sensor used in the study:

Sensor Name:
Problems / issues (if any):
Could the issues (if any) be resolved during the study? ☐ yes ☐ no
Has the collected data been provided to WP3? ☐ yes ☐ no
Number of data sets provided:

Sensor Name:
Problems / issues (if any):
Could the issues (if any) be resolved during the study? ☐ yes ☐ no
Has the collected data been provided to WP3? ☐ yes ☐ no
Number of data sets provided:

Sensor Name:
Problems / issues (if any):
Could the issues (if any) be resolved during the study? ☐ yes ☐ no
Has the collected data been provided to WP3? ☐ yes ☐ no
Number of data sets provided:

Appendix II Experimental plans

Experimental plan UCA

The UCA is focused on 8 safety drivers and their managers running a route with 3 Autonomous Vehicles (AV) called shuttles. The safety drivers work approximately half time as shuttle operators and half time as city bus drivers and/or tram drivers. The focus in PANACEA is to develop and evaluate a system that integrate sensors used to detect impairment and to avoid driving under impairment. Here alcohol/ drug use, fatigue and stress are of major interest, and the countermeasures that are relevant from a strategical, tactical and operative level. The main actors are bus drivers who are also safety drivers for autonomous shuttles. In total, 8 safety drivers (mixed age and gender) and 2 managers will be involved. There is one site manager and the staff managers.

UCA also includes a simulator study (UCA-S) performed in a driving simulator at the VTI premises in Linköping, Sweden to enable safe testing of driving under the influence of alcohol. Real-life data collection in the A6.3 and A6.4 study will be conducted with autonomous shuttles in the nearby Linköping University and Vallastaden area.

Simulator pilot UCA-S

The specific aims of the study are to:

1. Learn more about how moderate amounts of alcohol in the evening affects night sleep and next day driving performance.
2. Develop a first version of a biomathematical model of fatigue that takes next-day effects of alcohol into account.

Research questions

How does moderate alcohol intake in the evening affect night sleep and next day driving performance?

Can fatigue prediction using BMM be improved by taking next-day effects of alcohol consumption into account?

Participants

A total of 30 male drivers aged 25-50 years old were included in the study. Young males were selected to get a more homogenous study sample, and hangover severity declines with age and is more severe in men. Participants had a body mass index (BMI) below 35, since high BMI increases the likelihood of having undiagnosed sleep disorders.

Drinking habits were moderate with an AUDIT score of no more than 7, but with a score of 3 to 4 on the first question ("How often do you drink alcohol?", 2-4 times/month or 2-3 times/week). Participants with known sleep disorders, with known motion sickness problems, or with drinking problems as indicated by answers on the AUDIT questionnaire (>5 for women and >7 for men), were excluded.

Simulator

Fixed-base driving simulators consisting of three computer screens and a vehicle mock-up were used in the trials (Figure 1).

Two driving simulators were used so two participants could drive in parallel, and for each simulator, two participants drove sequentially. This added up to four participants per experiment day.

Figure 14. *Driving simulator environment.*

Simulator environment

The simulated environment consisted of two parts; a rural road (about 25 minutes) followed by an urban scenario (about 10 minutes). The first part was intended to be monotonous and fatigue inducing (to exploit the combined effect of alcohol and fatigue) while the second part was more active, requiring planning ahead for smooth progress. No surprises or occurrences requiring a fast reaction time were included.

Driver impairments

Alcohol intoxication was the main driver impairment in focus and the level of intoxication was manipulated as described below. Other impairments of interest were fatigue and stress.

Study design

The data collection consisted of two parts that takes place on different occasions in counterbalanced order. In one part, the participant came to the lab in the evening, made a baseline drive, drank alcohol, made an intoxicated drive, went home to sleep, and came back the next morning to make two next-day effect drives. In the other part, the participants did the two morning drives without alcohol in the evening.

Alcohol doses were determined based on Hume–Weyers formula, which estimates total body water based on height, weight and gender to determine the volume of alcohol required to reach a desired peak BAC level.

The study had a within-subject mixed-model design with a factor for next-day effects (driving with alcohol intake the day before versus driving without alcohol the day before) and a factor for time (in the morning and in the forenoon the day after). Participants will be treated as a random factor. A baseline condition was recorded in the evening and an intoxication condition was recorded after alcohol consumption. The targeted BAC level was 0.05% which corresponds to “social drinking”.

Data gathering tools

PANACEA sensors

Physiological/behavioural measurements:

- AIT smartPWA, 2-minute recording before and after each drive
  - ECG
  - PPG
  - Derived measure of fatigue, stress and cognitive load based on above

Actigraphy (Fitbit Charge 5), night between evening and morning drive.

Reference sensors

Physiological/behavioural measurements:

- Vitaport 3 (Temec Instruments BV, the Netherlands) continuously during the drive
  - Vertical EOG
  - ECG

- Smart Eye Pro (4-camera remote eye tracking) continuously during the drive
  - Eyelid opening
  - Gaze direction
  - Pupil dilation

Alcohol concentration:

- Dräger 6820 (Drägerwerk AG & Co, Lübeck, Germany), before and after each drive.

Other objective data gathering tools

Simulator data was logged continuously during the drive. Data from various sensors were logged, the most important being:

- Speed and speed variability
- Lane position and steering, including variability
- Surrounding traffic, including time headway and time to collision

Vigilance test, Psychomotor Vigilance Task (PVT) before and after each drive.

Questionnaires

Self-reportings:

- The Karolinska sleepiness scale, every fifth minute throughout the drives
- How intoxicated do you feel? (0: completely sober; 10 very affected), before and after each drive
- How well do you think you will drive? (0: worst imaginable; 10 best imaginable), before and after each drive
- How well did you drive? (0: worst imaginable; 10 best imaginable), before and after each drive
- Sleep diary before the trials
- AUDIT questionnaire and demographics before the trials

Data analysis plan

Analyse potential differences in fatigue/sleepiness as a function of time/distance and condition (6 drives – next day after alcohol 1, next day after alcohol 2, next day without alcohol 1, next day without alcohol 2, evening without alcohol, evening with alcohol). The indicators include: SDLP, THW, speed, KSS, HR(V), blink duration, eyelid closing velocity, PRC and pupil diameter.

Analyse potential differences in fatigue/sleepiness indicators when going from monotonous rural road driving to urban driving, as a function of condition.

Analyse potential differences in PVT indicators, smartPWA indicators and subjective driving ability with respect to the factors before/after driving and condition.

Model potential changes in driving performance due to intoxication and embed the model in the three-process model of fatigue.

Time plan

The data collection was performed in March and April 2022 (M11-M12).

Real-world pilot UCA-R

In this study the focus is on shuttle/ city bus drivers' health and working conditions. The objective is to evaluate and assess the CHT-A and its countermeasures addressing both shuttle drivers and the operators.

Research questions

The research questions relevant for UCA are:

- Do the PANACEA sensors/systems detect targeted driver impairments effectively with high sensitivity and specificity?
- Does the sleep/wake history (24h data) in combination with a BMM give the same information compared to the subjective before-driving rating used by Datik?
- Do the combined sensors improve driver state detection?
- Can sleep/wake history (24h data) in combination with a BMM be used to distinguish different types of fatigue (and thus give more accurate countermeasures)?
- Does the PANACEA integrated solution work in a real-life setting to detect impairment and deliver counter measures?
- Is it possible to get around using highly specific baseline/calibration recordings and still get accurate estimates of driver state?
- Are the PANACEA sensors/systems accepted by the users?
- Are the CHTs perceived as useful, satisfying, trustworthy, and easy to use?
- How willing are the participants to use wearable devices 24h a day? What is the data availability after an extended period (several months) of usage? Is it too intrusive?
- Why do drivers not engage with the CHT if they don't engage?
- What are the immediate effects of implemented countermeasures?
- Will the 24h data reveal poor sleep hygiene, and if so, is it possible to fix with the Panacea countermeasures?
- From iCloud System data is it possible to measure the effects (short-term and lifestyle) of an implemented countermeasure?
- Do the countermeasures for sleep related fatigue (while driving) work in a professional setting with tight schedules?
- Are drivers willing to sacrifice their breaks to do scheduled measurements and relaxations tasks?
- Is the PANACEA countermeasures system accepted by the users?
- To what extent do drivers/operators engage with the countermeasures delivered by the cloud-based system?
- Why do drivers not engage with the countermeasure if they don't engage?

- Does behaviour change/improve after the relevant countermeasure has been administered?
- Will the PANACEA countermeasures reduce driver impairment and improve the driver performance?
- Would it be possible to implement the PANACEA system in regular operation?
- Does the PANACEA system increase perceived (drivers) and reported (operators) safety?

Participants

8 safety drivers (1 female) employed at Transdev, but also the operator (one or two persons) responsible for the operation of the shuttles and responsible for the shift schedule and employer responsible person.

The major consideration in the safety driver's perspective are the impact of shift work and the need to interact with VRUs. In addition, due to the automation level of the shuttles, the normal driver's mission is somewhat changed that can result in underload and monotony, but there is also a risk for overload, distraction, and stress when handling several tasks at the same time. Focus needs to be maintained throughout shift as safety drivers bear the traffic responsibility in a legal and authorization perspective and always need to be present in the AV. See Figure 15.

Figure 15. *Safety operators onboard the autonomous vehicle (shuttle)*

The site manager talks to drivers if there are more generic questions, set up new operations, handles all different problems on daily basis and is responsible for incident and accident recordings and mitigations.

The staff manger plans and administrate the daily operations in line with the PTAs agreed contracts. But also sets up the shift schedules taking different drivers and projects perspective into consideration. In addition, they need to monitor existing regulation about hours of service and regulations, but also more generic working regulations.

Vehicles

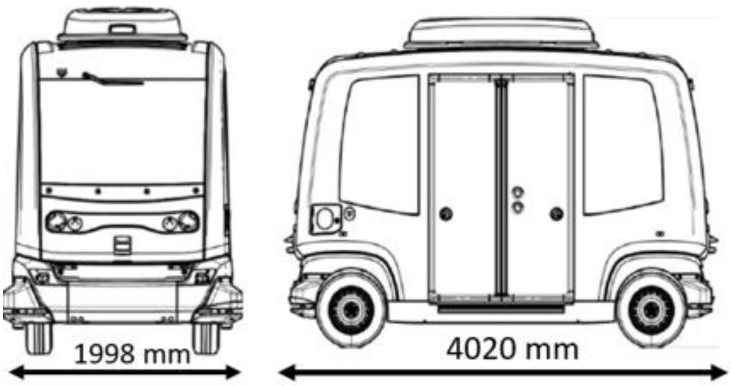
At the Linköping pilot site there are three AV shuttles from two different brands, two EasyMile EZ10 Gen-2 and one Navya DL4 Arma vehicle, see Figure 16. The AVs have a high level of intelligence and technology with LiDAR sensors, cameras, radar as well as GPS-devices for its localisation and position with high accuracy and allows for 5-6 passengers at the time. Due to legislation limitations their maximum allowed speed is 20 km/h.

For the data collection the two shuttles with the same brand (EasyMile) will be used. This approach was chosen to avoid confounding issues during the data collection due to different interior system, working conditions, vehicle behavior etc.

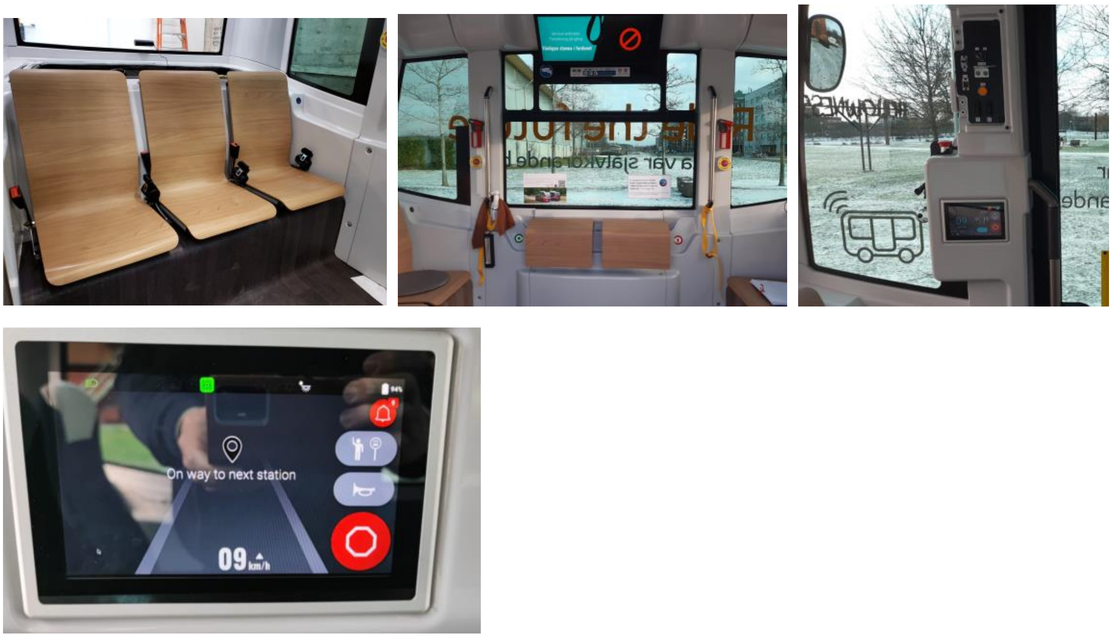
Figure 16. *The three AV shuttles in Linköping. The middle shuttle is a Navya DL4 Arma, the two on the sides are EasyMile EZ10 Gen2. Photo My Weidel, VTI.*

EasyMile EZ10 Gen2

The EasyMile shuttle is in a small-scale format. The EasyMile design is more obscured with fewer vehicle windows.



The layout in EasyMile also lacks a specific driving seat forcing the safety driver to be standing at all times.



Environment

The site consists of a 3.7 km long route including roads with both mixed traffic, meaning interaction with other motorized vehicles, but also a dedicated area with only pedestrians and cyclists allowed, see Figure 17. It covers a University campus and a residential area. In total there are 15 bus stops. The service is up and running 7 days a week according to a frequency-based timetable.

Figure 17. *An overview of the Linköping site (UCA)*

The geographical context is considered important to evaluate how the mobility service and its technology fits into a real-life context. Partly the University area are used to evaluate conflicts and interaction and collaboration with pedestrians and bicycles and how this affect the driver's behavior when there is a level of autonomy in the shuttle's programmed behavior, Figure 18.

Near the university there is a newly built residential area, Vallastaden. An area built to demonstrate a future concept for smart city, with relatively few parking spaces and an infrastructure optimized for walking and cycling. In Vallastaden there is also a school and a retirement home for elderly persons, Figure 19.

Figure 18. Showing Linköping's University campus area

Figure 19. *The residential area Vallastaden*.

Figure 20. *Explicit bus station for the shuttle service. Also showing landmarks on the bicycle street to inform and notify VRUs about the shuttle's existence*

The depot for the shuttles is located at VTI's backyard approximately 200 meters form the main autonomous line, Figure 21 and Figure 24.

The operator's main office is in the close city Norrköping, a close by city about 40 km from Linköping.

Figure 21. *Geographical context of shuttle operation in Linköping. Red cross represents the location of the garage for the shuttles*

When the safety drivers are operating the shuttles a standing driving position is always required in order to have a good visibility around the vehicle and to interact with the operator dashboard located next to the driver, Figure 22. In situations when the autonomous system cannot manage a specific traffic situation the driver overtakes the shuttle using a manual control unit to manoeuvre the shuttle. The manual control unit is of similar design as a game pad that is either connected with a cable or remotely connected, Figure 23. The working environment for safety drivers operating a shuttle is highly unique since there is no specific driver seat, turning wheel or brake pedals.

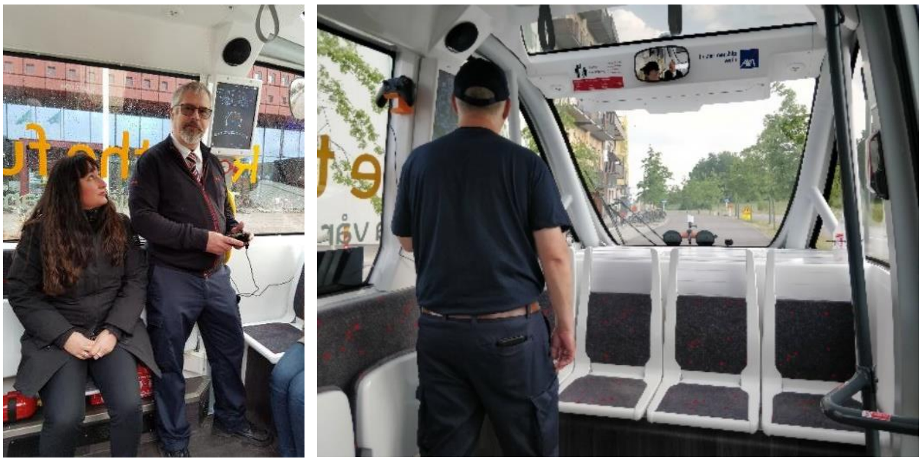


Figure 22. *Safety driver's position in the shuttle is close to the operator dashboard*

Figure 23. *Manual control unit for the shuttles. Connected by cable or by remote configuration*

Figure 24. *Storage and charging box for the autonomous shuttles*

Driver impairments

The focus on driver impairments in Linköping are: alcohol/drug use, fatigue and stress detection.

Countermeasures

For UCA safety drivers the selection of countermeasures defined in A5.2 are shown in Table 12.

Table 12. *Countermeasures addressing the safety drivers*

	Operational	*Tactical*	*Strategic*
UCA – Safety driver	**-Caffeine and napping advice for fatigue when sleepiness signs are detected**	**-Raising awareness of fatigue for drivers, providing sleep/recovery advice before/after work**	**-Lifestyle coaching relating to sleep and fatigue** (could inc. alcohol) -Lifestyle coaching for optimising rest (off duty)

	Operational	*Tactical*	*Strategic*
	-Self-management of stress/cognitive load during shift	*-Advice about alcohol use before work (not during shift) e.g., evening before*	time in terms of reducing stress and related fatigue

For UCA operator managers the selection of countermeasures defined in A5.3 are shown in Table 13.

Table 13. *Countermeasures addressing the manager*

	Operational	*Tactical*	*Strategic*
UCA – Manager	-Changing driver due to fatigue **-Changing driver due to alcohol** -Advice to operator on how to action results of DATIK pre-questionnaire (e.g., change driver/nap/caffeine) *-Providing facilities for rest breaks*	**-Advice/tools for Scheduling and how work is distributed within a shift** -Training on how to use and interpret PANACEA system -Training for managers in how to identify stress in drivers/when driving	**-Training and education on impact of alcohol and fatigue on driving** -Training and education on impact of licit/illicit drugs on driving *-Driver impairment risk management system* *-Establishing open culture to encourage reporting of PANACEA related impairment*

Study design

The study will have a within-subject design with a factor for baseline (driving with the detection system activated for data collection only) versus driving with the PANACEA system activated (both detection and countermeasures). The data collection will be conducted for an extended period of time in real-life operations of the shuttle service in Linköping, Sweden.

The data collection consists of three parts that takes place on different occasions. It will not be counterbalanced, since there is no way to guarantee that the shuttle drivers are not influenced by the system, especially the countermeasure part. The baseline data collection will take place approximately 1 month before the data collection with the system activated. The data collection with the system activated will last for 2 months, where the first month will be used to tune the system and the second is seen as the month where evaluations will take place. During the evaluation phase the drivers will report, on a daily basis, how they experience the systems in terms of detections/countermeasure performance perspective.

A more detailed outline of the procedure is presented in Table 14.

Table 14. *Experiment procedure.*

Baseline *(1 month)*	*PANACEA Activation* *(Month 1)*	*PANACEA Evaluation* *(1 month)*
1. An introduction meeting providing the drivers with information about the project, the study and the devices that will be included. 2. Signature of informed consent 3. Handout wearable sensors and instructions 4. Installation of PANACEA web application on their smartphones (provided by Transdev). 5. Provide a clear timetable for baseline data collections. 6. Collection of driver profile information. 7. Provide background survey including Audit, KSQ, stress, quality of life and drug use. The data will be collected at the introduction meeting. 8. The drivers start to use the PANACEA system and sensors, without the countermeasures, and continue using it for one month.	1. A physical meeting with the test leader that inform about the PANACEA countermeasures system that will be activated. 2. Test leader activates the full PANACEA system. 3. The data collection starts.	1. After 1 month the drivers will meet the test leader. Pros and cons with the system are collected. 2. The drivers are informed about the evaluation app and how to fill in this. 3. The drivers continue to use the system for 1 month more. 4. The drivers meet the test leader to give his/her feedback on the final survey. 5. Information for incentive administration is done.

Data gathering tools

PANACEA sensors

The PANACEA technologies used in the study are Datik FitDrive and pre-questionnaire, Leitat biosensor, Senseair Wall mounted, AIT smart PWA, Fitbit, BMM, Backtrack Skyn, and the countermeasures system.

Other objective data gathering tools

Questionnaires

Participants will answer the background questionnaire (see Appendix IV of D6.2) before the data collection starts, this is to get a better understanding of their working days, type of shifts, their normal use of alcohol/drugs, experience of stress, and fatigue and sleep problems. They will be given the QR code with a link to the questionnaire at the introduction meeting after they have signed the informed consent.

During the 2nd month with the full PANACEA system activated, an extra evaluation app will be used by the safety operators to report their experiences of the system. The reporting will take place at the end of the shift together with all daily reportings that always take place during shuttle operation. The daily evaluation questions can be found in Appendix IV of D6.2.

After the study the participants will be asked to answer the evaluation questionnaire (see Appendix IV of D6.2) with question on acceptance, satisfaction and usability in relation to the system they just perceived. The questionnaire also includes follow-up questions on sleep problems, stress symptoms, quality of life that can be compared with the baseline questionnaire. This will be completed once in the end of the pilot. Managers will only complete the questions about the system, not the health-related questions.

Focus groups

Focus groups with stakeholders will be performed after the final evaluation. The evaluation of longer-term countermeasures and training content will be performed in dedicated focus groups with both bus drivers and operators/mangers.

Data analysis plan

The drivers' self-ratings of sleep, sleepiness, stress, alcohol and drug use, and risky behaviours will be compared between the before (baseline) and after (evaluation) assessment. Usage data will be analysed and presented for the CHTs and countermeasure system. Opinions about the CHT and countermeasures will be analysed from the evaluation questionnaire and compared with established cut-offs, if available. Given the relatively small number of participants in the UCA-R study, most of the analyses will be descriptive. Further analyses will be made with the consolidated dataset in A6.5.

Recordings from the focus groups will be analysed qualitatively to get a deeper understanding of how a solution like PANACEA would work in regular operation.

Time plan

The baseline data collection will start in beginning of January 2023 (given that that the ethical application has been approved) and the PANACEA data collection will occur during spring 2023.

Experimental plan UCB

Pilot B involves the conductions of user tests with 20 taxi drivers and 20 delivery service riders with the passenger car driving and motorcycle simulators in the driving and riding laboratories at CERTH premises, respectively. The focus in PANACEA is to develop and evaluate the Commercial Health Toolkit (CHT) B as part of the PANACEA solution by integrating the primary and using the secondary technologies as those are presented and highlighted in Table 10 of D6.2. by using the technologies that will detect impairing (alcohol, drugs) and driver (fatigue stress, distraction) states.

Two pilot sites will participate in A6.2, the site in Thessaloniki, Greece (CERTH) and the site at Austria (ViF). It includes the CERTH and ViF driving and the CERTH riding simulation laboratories (A6.2, A6.3 and A6.4). The A6.3 and A6.4 activities will be conducted in the simulators due to ethical and legal restrictions (potential consumption of alcohol and drugs will be included) and because it allows for an in-depth performance evaluation of the PANACEA solution (internal validity). Initially, it was planned to use the instrumented vehicles for a short drive around the premises for fatigue and stress and alcohol and drugs (replacement) in the simulator. However, as this would demand to participants to experience the solution in two different environments, it was decided to conduct the tests on simulators and focus on the internal validation of the PANACEA solution, whereas UCA and UCC would focus on the external validation; hence address both in the evaluation activities of the project. However, for those technologies that continuous data collection is possible (FitDrive for fatigue and BACtrack for alcohol) and are primary impairments/ states in the project, the semi-real-life testing will take place with a selected sample of drivers and riders.

Simulator study UCB-S1

Objectives

The objectives for A6.2 pilots are to collect data for the refinement of the algorithms developed in WP3 and to ensure that the selected levels for the impairing and driver states are meaningful and measurable with targeted accuracy, sensitivity and specificity.

These will be further refined based on selected research questions and KPIs.

Site description

The infrastructure for the simulator pilots are the two passenger car simulators in CERTH and ViF premises, the motorcycle simulator (Figure 25) at CERTH and the instrumented passenger car and motorcycle for the real-life tests inside the CERTH premises (Figure 32).

Fatigue, alcohol consumption and stress will be addressed in A6.2 pilots in Thessaloniki, Greece and distraction in Austria. Fatigue and stress will be addressed in semi-real-life conditions in A6.3/A6.4 pilots and alcohol and drugs will be addressed only in simulated environment due to legal and ethical restrictions.

Research questions

- How do fatigue levels change across the working shift?
- How do stress levels change across the shift?
- How do the measurements of the DATIK system and Optalert match?
- Will addressed levels of driver state and/ or impairment be captured?
- How do the measurement of SENSEAIR and BACtrack skyn match?
- Does the AIT Pulse Wave Analysis (PWA) device and Galvanic Skin Response (GSR) sensors' measurements match?

Participants

20 taxi drivers and 20 delivery service riders will participate in the simulator tests with good or corrected eyesight. Equal gender or at least population representation will be sought. Written informed consent will be obtained prior any participation. Data collection will be anonymised. Researchers will not have any access to the participants' personal data. Recruitment and consent will be divided from actual test conduction.

Simulators

The **driving simulator** is a dynamic car simulator with a complete road car (SMART) on a rotating platform (Figure 3; left). The platform allows roll and pitch motion used also as motion cue for simulation of acceleration and braking. The visual system of the simulator is based on five projection screens that surround the field of view of the driver. The instrument cluster and all the controls are functioning on the car and used by the simulator. The simulator allows the performance of repeatable experiments in controlled conditions. The scenario editor allows the creation of custom traffic scenarios with control over the traffic environment (urban, rural, highway), the behaviour of the other road users, the weather and light conditions. The ego-vehicle can simulate the dynamics of other cars apart from the SMART as well as Electric Vehicles, trucks, buses and special vehicles (ambulance, fire truck).

Autonomous vehicles can be simulated with prescribed motion of the ego-vehicle or Wizard of Oz methodology. The simulator is used in studies for critical situations (near accident incidents), driving behaviour, HMI studies, elderlies' driving skills assessment, influence of medicines on driving performance and safely testing new equipment for vehicles.

Figure 25. *Driving simulator (left) and riding simulator (right)*

The **riding simulator** is a dynamic motorcycle simulator (Figure 3; right). The simulator dynamics allow five degrees of freedom (roll, pitch, yaw, handlebar extension and shortening). The visual system of the simulator employees three projection screens that cover the riders' field of view and an instrument panel with an LCD screen that presents information through the simulator CAN bus and can be also used on a motorcycle. The audio system of the simulator consists of five speakers and a subwoofer with spatial audio. The environmental climatic conditions of riding are simulated with a large fan in front of the simulator, a powerful heat pump, halogen lamps for heat radiation and humidifiers. The simulator allows the reproduction of various types of powered two wheelers with different configurations both in the motorcycle geometry and vehicle dynamics. The traffic simulation software allows the development of scenarios with other vehicles in urban, rural and highway environment in various weather and light conditions (dawn, daylight, dusk, night). The simulator allows safe and repeatable experiments in controlled conditions. All the motorcycle controls of the simulator are recorded in addition to the motorcycle dynamics and surrounding traffic. Additional hardware can be connected and synchronized with the simulator either through CAN bus, Bluetooth or serial port. The simulator has been used in Hardware in the Loop (HiL), Human in the Loop (HITL), rider behaviour, HMI, biomechanics and thermal comfort experiment as well as tuning, validating and evaluating new motorcycle equipment before testing it on the road.

Simulator environment

Test sessions will be held in the driving car and riding motorcycle laboratories at CERTH/ HIT premises. The simulator environment differs per state as follows:

Fatigue: Monotonous peri-urban environment with change from day to night.

Stress: Urban with increasing traffic and several events on road.

Alcohol: Peri-urban, urban with traffic with and without events.

Each driving session will start with a 5- minute familiarisation phase. The driving session will last 30 minutes.

Driver impairments

Fatigue, alcohol consumption and stress will be addressed in A6.2 pilots in Thessaloniki, Greece.

Study design

A repeated within-participants design is applied with baseline measurements collected at the first session. Consent is obtained prior participation and any questions are answered prior the testing session. All participants are coded. They participate in three counterbalanced sessions, one before their shift starts, one after their shift ends and once, they arrive at the middle of their shift. Each state is measured by the PANACEA technologies and a reference technology.

Fatigue will be measure before, after the session and continuously. Stress will be measured before and after the session, continuously (GSR) and triggered (elicited by event and/ or GSR measurements). Alcohol will be measured at 4 levels in three sessions (0, 0.02%, 0.05%, >.05%). Fatigue and stress scales will be administered before and after the session and for stress after events. Reference technologies for fatigue (EEG, ECG), for stress (ECG) and for alcohol (Draeger breathalyser used by police force).

The procedure is presented in the table below.

Table 15. *UCB – S1/ S2 design and procedure*

Part of session	Time
Informed consent	-20 mins
Briefing and ethical rights	-5 mins
BASELINE & pre-shift (1st session)	**0 mins**
Pre-questionnaire completion on fatigue, stress and alcohol use.	10 mins
Driving/ Riding simulator familiarization	5 mins (only during their first session; sessions will be counterbalanced)
Fatigue, stress, alcohol baseline measurements (this includes 0% level alcohol) are taken.	30 mins (including 10 mins setting up and measurement collection) and collection with both reference and PANACEA technologies and 20 mins driving/ riding simulator.
Alcohol consumption (0.02%)	20 mins
Post questionnaire completion on fatigue, stress and alcohol state. Incl. some question items on the technologies (in the first session).	15 mins
Checking data collection status and quality	5 mins (in parallel with debriefing)
Debriefing	5 mins
During Driving/ Riding (2nd session)	**0 mins**
Pre-questionnaire completion on fatigue, stress.	10 mins
Driving/ Riding simulator familiarization	5 mins
Simulator fatigue driving/ riding scenario	20 mins
Post question completion on fatigue, stress	10 mins
Simulator stress driving/ riding scenario	20 mins
Post question completion on fatigue, stress	20 mins

Part of session	Time
Debriefing	5 mins
Post- shift (3rd session)	**0 mins**
Pre-questionnaire completion on fatigue, stress and alcohol	10 mins
Driving/ Riding simulator familiarization	5 mins
Simulator fatigue driving/ riding scenario	15 mins
Post question completion on fatigue, stress and alcohol	10 mins
Simulator stress driving/ riding scenario	15 mins
Post question completion on fatigue, stress	10 mins
Simulator alcohol (>0.05%) driving/ riding scenario	20 mins
Post questionnaire completion on fatigue, stress and alcohol	10 mins
Checking data collection status and quality	5 mins (in parallel with debriefing)
Debriefing	5 mins

Data gathering tools

- Data are logged in ASCII files (lateral position and deviation, speed and variability, headway, time-to-collision, brake and response time, etc).
- Physiological/behavioural measurements
  - AIT smartPWA:
    - ECG
    - PPG
- Alcohol concentration
  - BrAC (Senseair wall-mounted and Go) and BACtrack skyn wearable (TAC) and breathanalyser (BrAC)
- DATIK system:
  - Pre-questionnaire data
  - Fatigue events
  - Other data
- Optalert glasses:
  - Fatigue score (KSS)
- GSR
  - Skin conductance data (cleaned from noise)
- Subjective scales/ questionnaires:
  - The Karolinska sleepiness scale (KSS), the stress scale

    - Self-assessment of driving quality
    - Background and demo questions (during debriefing)
- Other scales.

Data analysis plan

Data collection is performed for WP3 purposes. Data quality and completeness check after each session. Data will be sent to the technology providers Measuring of fatigue levels achieved and investigate if there are any differences between the reference, the technologies and the subjective scale addressing the same impairment and/ or driver/ rider state.

Time plan

The A6.2 pilots will be conducted in between February and March 2023. The pre-testing sessions will take place two weeks before they start. It is expected that the technologies involved will be technical verified and validated (within WP4) before the pre-testing sessions.

Simulator study UCB-S2

Main aim of the simulator study at VIF was to investigate different types of driver distraction (cognitive, visual) in different driving environments (city vs. highway) to collect data for the development of a multisensory fusion algorithm for detecting a distracted driver state.

Research questions

- What sensor data are the best driver state behaviour impairment indicators?
- Which combination of algorithms can best capture impaired driving in the respective environment?
- What are the critical differences in detecting impaired driving in city traffic versus motorway / country road traffic?

Participants

In total we had 42 participants of which most were experienced drivers. With a distribution of 22 male and 20 female participants, gender distribution was largely equal. Age ranged from 18 to 69 with an average of ~26 years.

Simulator

Simulator environment

For the study, two different simulator environments were used: a city and a highway environment. For standardization purposes participants drove in both environments mostly straight. To increase credibility of the environments we placed certain obstacles and traffic elements fitting the environment, such as traffic lights, jaywalking passengers and 30 kph signs in the city; and 100 kph signs in the highway environment.

Visually the environments differed based on the surroundings (buildings in the city; trees and hills in the highway), as well as the infrastructure (crossings and roundabouts in the city; a few exits and entries in the highway).

Driver impairments

Driver distraction was the main impairment investigated and induced in the study. Three different distraction types were induced with three different secondary tasks:

- Visual-Manual distraction was induced with a self-paced version of the SURT (surrogate reference task) presented on a tablet. In this task participants look for a slightly larger circle in a set of equally large circles. Once they found it, they press on it with their finger and a new set is presented.

- Cognitive distraction was induced with a medium difficulty version of the ACPT (auditory continuous performance task). Participants were presented with a spoken list of letters. They had to react to a certain pattern in the letters, namely an “A” which was preceded by a “Q” four letters prior. This task was not self-paced, meaning letters were presented for some time in a certain frequency independent of the participant answer.

- Cognitive-Visual distraction was induced with a standardized matrices task as presented in typical IQ questionnaires. Participants were presented with a 3 * 3 matrix of different symbols with a certain pattern in their arrangement, where one symbol is missing. Beneath the matrix a numbered set of 6 to 8 different other symbols are shown, of which one logically fits in the pattern of the above matrix. Participants had to loudly say the number of the correct symbol. Once a participant said a number, another matrix was presented.

Additionally, we defined “focused driving” as a type of non-distraction. Here drivers were instructed to drive fully focused for some time.

Study design

The study was realized as permutated within-subjects design with two independent variables: (1) the *kind of driving environment*: city vs. highway, and (2) *kind of driver distraction*: cognitive vs. visual/manual vs. cognitive/visual. The tasks to induce the different distraction types were performed in permutated order during the drive.

As dependent variables, different parameters were measured to capture the behaviour and state of a driver (see Figure 26 for an overview). Primarily, we focused on parameters capturing gazing behaviour (e.g., temporal gaze variance, gaze off road), driving behaviour (e.g., steering wheel angle, SD headway, whether the hand(s) are on/off the steering wheel, stress, and cognitive load. In addition, subjective measures such as perceived distraction or stress were captured after each drive.

Figure 26Figure 10 provides an overview of the study procedure. The participant was welcomed and after signing the informed consent and filling in a demographic questionnaire, the different tools for capturing the data were prepared. The participant then performed a practice drive to familiarize with the driving simulator. This was followed by a baseline drive to capture the baseline data for the algorithms. The participant was introduced to the secondary distracting tasks to be performed during the drive and then performed a drive (order permutated per subject) in the respective environment city or highway.

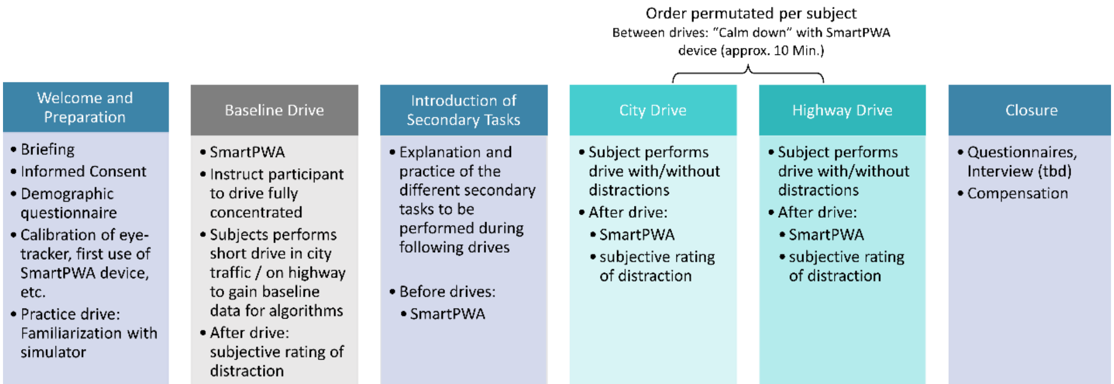


Figure 26. *Planned study procedure for the VIF simulator study*

During the respective drive the participant was asked to perform the different secondary tasks during predefined time intervals. For better understanding, Figure 27 shows the different drives and in red colour the segments of when the distraction tasks and the focused driving were given in permutated order. The start and end of the respective task were logged in the data along with the other measurements.

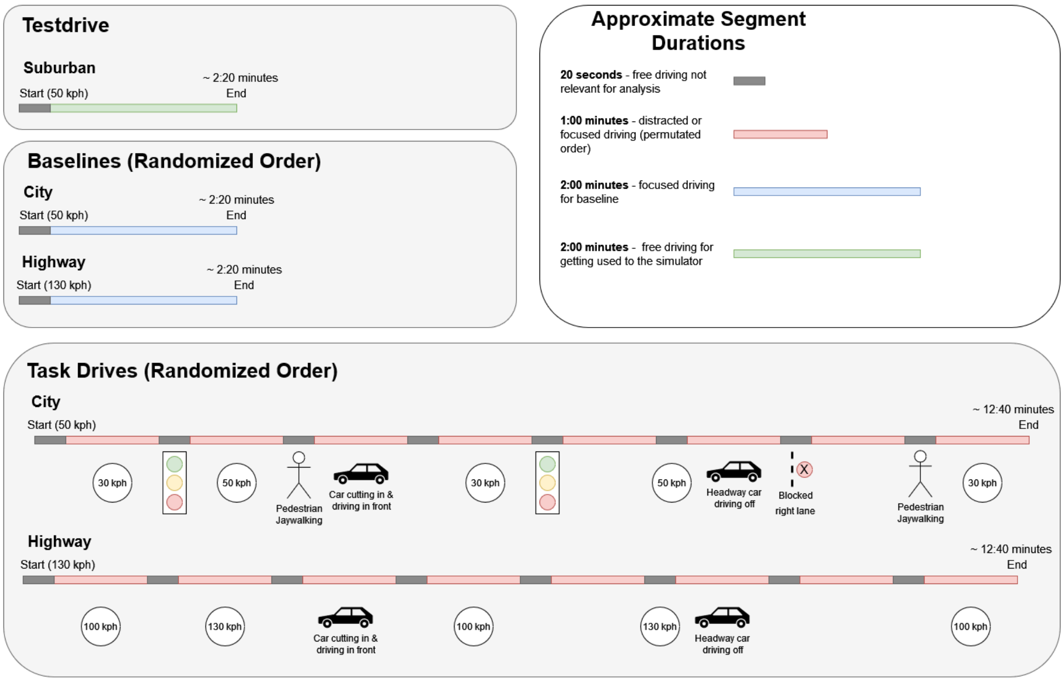


Figure 27. *Schematic visualization of the different drives and the distraction segments. Additionally, all environmental obstacles are shown in symbolic form*

Data gathering tools

Table 16 provides an overview of the data collection tools and parameters that were captured with those tools. Note that parameters in bold require the application of a predefined analysis algorithm. Measurements with the smartPWA device only took place at predefined points in time during the study (see Figure 10), while all other measurements were based on continuous measurements during the drive. VIF's Data.Beam was used to synchronize all data from the different sensors.

For reference we used the cognitive load and vigilance parameters from the EEG device provided by DeepBlue.

Table 16. *Data collection tools and parameters in the VIF simulator study*

Data Collection Tool	Parameters
Eye-Tracking System (SmartEye)	• **Temporal gaze variance** • **Gaze off road (AttenD)** • Gaze variance on road • Blink-rate • Fixation duration
Camera	• **Hand off wheel**
Simulator	• Steering Wheel Angle • SD Headway • SD Lateral Position • SD Speed

Data Collection Tool	Parameters
EEG (provided by DBL)	• **Cognitive Load** • **Vigilance**
SmartPWA (provided by AIT)	• **Stress** • **Cognitive Load**
Karolinska Sleepiness Scale DALI	• Sleepiness • Workload

Data analysis plan

The data gathered in the study will in a first step be used to build various individual distraction metrics, which afterwards are analysed for their individual predictive information for different types of driver distraction. The next step consists of combining those metrics and building different types of systems classifying the situational distraction state of a driver. The main distraction detection method will consist of a machine learning system which will be informed by behavioural theories and hand-crafted rules derived from literature and previous studies at ViF. If applicably, the data will be supplemented by the data from previous studies in a last step to increase the dataset fed to the AI. This will allow for the design of a more explainable machine learning model to detect driver distraction.

Time plan

The study was conducted in February/ March 2022. The data pre-processing, analysis, and fusion is planned to be finished by end of February 2023.

Simulator study UCB-S3 and R1/R2

The primary actors involved are taxi drivers and courier service riders and their operators. Other stakeholders, as defined in D1.1 will be involved in focus groups and interviews held to accommodate for the A6.3 and A6.4 requirements.

Research questions

Evaluate and assess the CHT-B and its countermeasures addressing both taxi drivers, delivery service riders and operators. The latter will participate in focus groups.

- Do the PANACEA sensors/systems detect targeted driver impairments effectively with high sensitivity and specificity?
- How is the performance of the PANACEA sensors compared to a reference measurement?
- How is the performance of the LEITAT sensor compared to the commercial drug sensor used by the Police in Norway?
- How is the performance of the SENSEAIR Go Portable compared to the commercial alcohol sensor used by the Police in Norway?
- How is the performance of the LEITAT sensor compared to the blood tests used by the Police in Norway?
- How do the measurements of the DATIK system and Optalert match?
- How do the measurement of SENSEAIR and BACtrack skyn match?
- Does the AIT Pulse Wave Analysis (PWA) device and Galvanic Skin Response (GSR) sensors' measurements match?
- Will addressed levels of driver state and/ or impairment be captured?
- What sensor data are the best driver state behaviour impairment indicators?
- Which combination of algorithms can best capture impaired driving in the respective environment?
- What are the critical differences in detecting impaired driving in city traffic versus motorway / country road traffic?
- Is the LEITAT/SENSEAIR Go Portable sensor reliable and easy to use in roadside assessments?
- Do the combined sensors improve driver state detection?
- Does the PANACEA integrated solution work in a real-life setting to detect impairment and deliver counter measures?
- Is it possible to get around using highly specific baseline/calibration recordings and still get accurate estimates of driver state?
- Are the PANACEA sensors/systems accepted by the users?
- Are the CHTs perceived as useful, satisfying, trustworthy, and easy to use?

- How willing are the participants to use wearable devices 24h a day? What is the data availability after an extended period (several months) of usage? Is it too intrusive?
- Why do drivers not engage with the CHT if they don't engage?
- What are the immediate effects of implemented countermeasures?

Participants

The criteria are the same as for UCB-S1 and the same participants will be sought to participate as much as possible. Gender distribution is considered; female representation is low in taxi drivers and even lower in courier service delivery riders. Methadone participants will receive their drug replacement therapy at the allocated public rehabilitation center and they will arrive to the CERTH premises 8 hours after the intake. A doctor will be present during the experiments (A6.2-A6.4).

Vehicles

The simulators are the same as in UCB-S1 drivers and riders and technical set up is shown below (Figure 28 and Figure 29).

Figure 28. *Technical set up driving simulator*

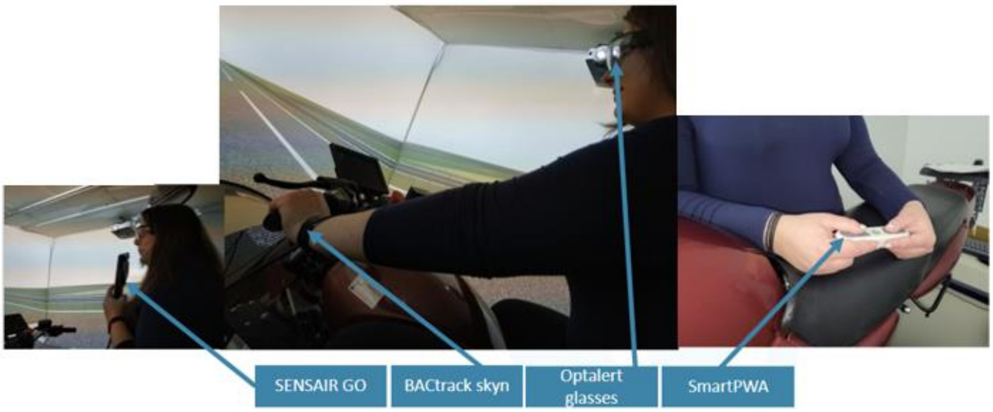


Figure 29. *Technical set up riding simulator*

Instrumented vehicles

An F-segment, large sedan (Lancia Theta; Figure 30). This car is very spacious both for passengers and research equipment. It is equipped with co-driver pedals and can be used on the road under the supervision of a second driver. The car is instrumented with driver monitoring sensors (cameras, eye tracking sensors, ElectroEncephaloGraph(EEG), head tracking, seat pressure pads), car monitoring (CAN bus recording equipment with the car CAN database) and it can support industrial and desktop computers with a 220V inverter. The car has integrated Human Machine Interface (HMI) solutions with (seatbelt vibration, infotainment screen, visual and audio warnings). Additionally, it has radar and LIDAR preinstalled for Advance Driver Assistance System (ADAS) applications. The car has been used for development of algorithms for drowsiness detection, driver behaviour studies, ADAS systems validation and C-ITS (Cooperative-Intelligent Transport Systems) applications.

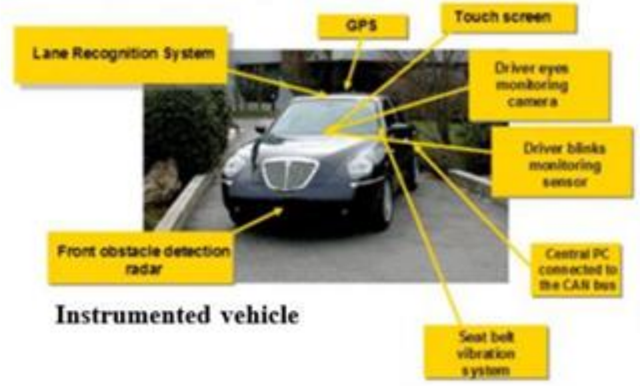


Figure 30. *The instrumented car*

A conventional street motorcycle (KTM Duke; Figure 31). The motorcycle is instrumented with sensors for monitoring the kinematics of the motorcycle (position, velocity, acceleration, motorcycle lean angle, steering angle, suspension displacement) and the rider (torso and head kinematics, handlebar and footrest forces) and is used in experiments for studying rider kinematics during evasive manoeuvres.

Figure 31. *The instrumented motorcycle*

Environment

FitDrive (fatigue for 5 drivers) and BACtrack skyn (alcohol use 3 number of hours before for 5 riders) will be conducted in the CERTH area, as shown in Figure 32. The real-time alcohol consumption and methadone (drug replacement) tests will be conducted in the CERTH riding and driving simulators also for ethical and legal reasons.

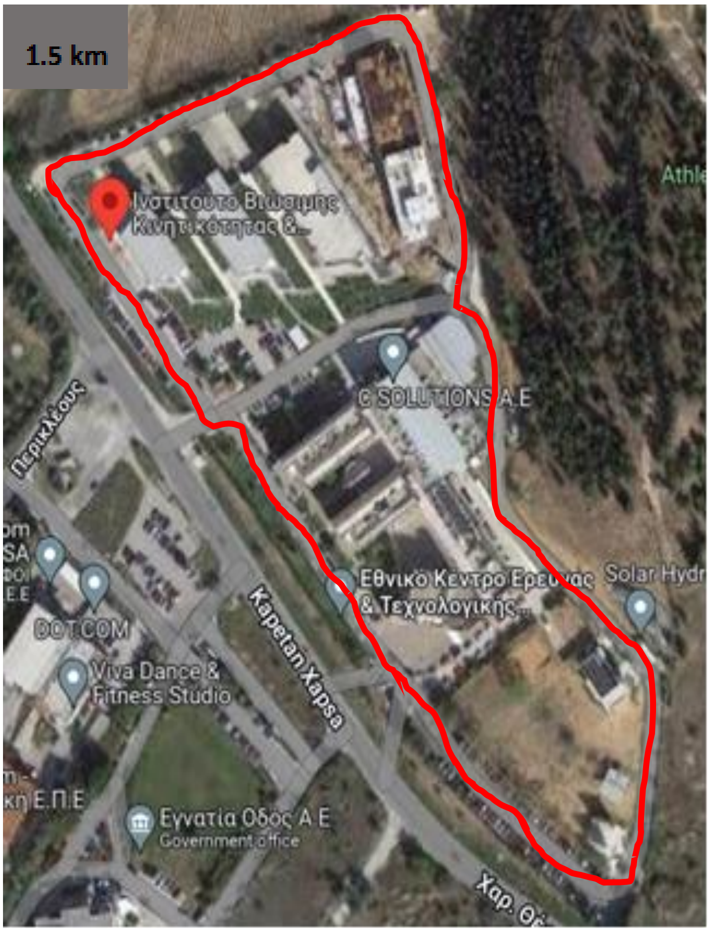


Figure 32. *Real-life tests route at CERTH premises*

The route consists of a 1.5 km long route with minimal interaction with other vehicles and controlled interaction based on pre-selected scenarios that resembles peri-urban road conditions. These routes have been used in the past to demonstrate rider and driver conspicuity and interaction scenarios, therefore there is adequate versatility with control over safety and risks. In addition, pedestrians, cyclists and it covers the grounds of the peripheral roads of CERTH. For these tests the instrumented research car and PTW will be used (Figure 32).

Driver impairments

Fatigue and post-alcohol intake will be tested in semi-real-life conditions in A6.3/A6.4 pilots and all addressed impairments and states as well as countermeasures in simulated environment due to legal and ethical restrictions and for assessing the performance of the PANACEA solution in one environment for holistic performance, ethical and legal issues.

Countermeasures

The tables that follow present the selected countermeasures for UCB drivers/ riders (Table 17) and operators, respectively (Table 18). The process to reach this selection is presented in MS13 document.

Table 17. *Suggested countermeasures for drivers/ riders*

	Operational	Tactical	Strategic
UCB	**-Self-management of stress/cognitive load during shift (could inc. headway management)** **-Guided breathing exercises**	**-Advice about licit drugs prior to shift (taken the night before a morning shift or in the morning of a morning shift) focus on immediate and residual effects**	**-Lifestyle coaching relating to stress and cognitive load** *-Lifestyle coaching relating to prescription drugs*

Table 18. *Operators' countermeasures*

	Operational	Tactical	Strategic
UCB	**Advice to operator on how to action results of DATIK pre-questionnaire (e.g., change driver/nap/caffeine)**	Training on how to use and interpret PANACEA system *Medical assessment when drivers join company - licit drugs*	**Training and education on impact of licit/illicit drugs on driving** **Training and education on medication management** Training and education on impact of alcohol on driving

Study design

The study will have a within-participants' design and it will be the same for drivers and riders. However contrary to A6.2 pilots not all participants will experience all technologies, but they will be selected for drivers and riders. 15 drivers and 15 riders will participate in the evaluation of the PANACEA solution. From those participants, 5 drivers (with FitDrive) and 5 riders (with BACtrack skyn wearable) will participate in the semi-real-life tests to evaluate the experience of a continuous monitoring through the PANACEA solution in real life setting from the ones that have already experienced the PANACEA solution in the simulator studies. A discussion will follow on the differences in experience and perceived performance.

Another 10 drivers/ riders under methadone rehabilitation will participate in the simulator studies for drug detection. The technologies available to drivers through the PANACEA solution will be: FitDrive (fatigue), Driver Monitoring System (distraction), GSR sensor (stress), AIT device (stress), SENSEAIR wall mounted and Go (alcohol). The technologies available to riders will be AIT device (stress), BACtrack skyn (alcohol), optalert glasses (fatigue). From the technologies used in the simulator tests, FitDrive (fatigue) will be tested in the simulator and semi-real-life condition for drivers as well as BACtrack skyn (TAC alcohol detection) will be used in the semi-real-life conditions with the instrumented PTW.

Table 19. *UCB – S3 procedure* (driving / riding simulator)

Part of session	Time
Informed consent and Background questionnaire	-30 mins
Briefing and ethical rights	-5 mins
BASELINE & pre-shift (1st session)	**0 mins**
Driving/ Riding simulator familiarization	5 mins (only during their first session; sessions will be counterbalanced)

Part of session	Time
Fatigue, stress, alcohol baseline measurements (this includes 0% level alcohol) are taken.	30 mins (including 10 mins setting up and measurement collection) and collection with both reference and PANACEA technologies and 20 mins driving/ riding simulator.
Alcohol consumption (0.02%)	20 mins
Checking data collection status and quality	5 mins (in parallel with debriefing)
Debriefing	5 mins
During Driving/ Riding (2nd session)	**0 mins**
Driving/ Riding simulator familiarization	5 mins
Simulator fatigue driving/ riding scenario	20 mins
Simulator stress driving/ riding scenario	20 mins
Administration of stress countermeasure	5 mins
Simulator distraction driving/ riding scenario	20 mins
Debriefing	5 mins
Post- shift (3rd session)	**0 mins**
Driving/ Riding simulator familiarization	5 mins
Simulator fatigue driving/ riding scenario	15 mins
Simulator stress driving/ riding scenario	15 mins
Administration of stress countermeasure (operational)	5 mins
Simulator alcohol (>0.05%) driving/ riding scenario	20 mins
Checking data collection status and quality	5 mins (in parallel with debriefing)
Administration of stress countermeasure (operational)	10 mins
Countermeasure for stress (strategic)	5 mins
Post-questionnaire: Technology acceptance and SUS scales for PANACEA solution	10 mins
Debriefing	5 mins

The following table presents the simulator tests with the drug replacement (methadone) participants.

Table 20. *UCB – S3 procedure* **–** illicit drug replacements (driving / riding vehicles)

Part of session	Time
Informed consent and Background questionnaire	-30 mins
Briefing and ethical rights	-5 mins
8 hours Post – dose (driver/ rider)	**0 mins**
Drug testing	5 mins
Driving/ Riding simulator familiarization	5 mins (only during their first session; sessions will be counterbalanced)
Driving/ riding scenario	20 mins
Countermeasure (tactical)	10 mins
Post-questionnaire: Technology acceptance and SUS scales for PANACEA solution	15 mins

Part of session	Time
Checking data collection status and quality	5 mins (in parallel with debriefing)
Debriefing	5 mins

The following table presents the semi-reallife tests for fatigue and post-alcohol measurements only.

Table 21. *UCB – R procedure* (driving / riding vehicles)

Part of session	Time
Post – shift (driver/ rider)	**0 mins**
Driving/ Riding vehicle familiarization	5 mins (only during their first session; sessions will be counterbalanced)
Post- shift (3rd session)	**5 mins**
Fatigue measurement (FitDrive) or Alcohol BACtrack wearable (alcohol) – 3hours after alcohol intake (>0.05%)	20 mins
Post-questionnaire: Technology acceptance and SUS scales for PANACEA solution (for those who participated in both simulated and semi-real tests (i.e., 10 in total), they will be completed here, for the rest after the simulated experience.	15 mins
Checking data collection status and quality	5 mins (in parallel with debriefing)
Debriefing	5 mins

Data gathering tools

PANACEA sensors

The PANACEA technologies used in the study are Datik FitDrive and pre-questionnaire, Leitat biosensor, Senseair Wall mounted, SENSEAIR Go, AIT smart PWA, Backtrack Skyn, VIF driver monitoring system, Optalert glasses, GSR sensor and the countermeasures system.

Other objective data gathering tools

Simulator data was logged continuously during the drive. Data from various sensors were logged, the most important being:

- Speed and speed variability
- Lane position and steering, including variability
- Surrounding traffic, including time headway and time to collision

Questionnaires

Participants will answer the background questionnaire (see Appendix IV of D6.2) before the data collection starts, this is to get a better understanding of their working days, type of shifts, their normal use of alcohol/drugs, experience of stress, and fatigue and sleep problems.

After the end of the end of all sessions, they will evaluate the PANACEA solution (see Appendix IV of D6.2) with question on acceptance, satisfaction and usability in relation to the system they just perceived. The questionnaire also includes follow-up questions on sleep problems, stress symptoms, quality of life that can be compared with the baseline questionnaire.

Focus groups with addressed actors will be conducted after the final evaluation. The evaluation of longer-term countermeasures and training content will be performed in dedicated focus groups with both taxi drivers and operators/managers. Likewise, for delivery service riders and operators. The focus groups will be designed to highlight aspects of the experimental procedure that have inherent gaps and include the operators/ managers in the process. Thus, they will be prepared and conducted after the end of the pilots.

Data analysis plan

Background and post-evaluation self-reported questionnaire will be used to evaluate the experience of participants with the system in relation to their background as well as the impairments/ states addressed. The countermeasure system will be subjectively evaluated. Usage data will be analysed and presented for the CHTs and countermeasure system. Opinions about the CHT and countermeasures will be analysed from the evaluation questionnaire and compared with established cut-offs, if available. Analyses will be descriptive and inferential. Further analyses will be made with the consolidated dataset in A6.5.

Recordings from the focus groups will be analysed qualitatively to get a deeper understanding of how a solution like PANACEA would work in regular operation. Operation countermeasures will be evaluated separately with operators/ managers from the taxi company and the delivery service company through the focus groups.

Time plan

The experiments will start May 2023 (given that that the ethical application has been approved) and the PANACEA data collection will continue until July 2023.

Experimental plan UCC

The UCC is focused on professional drivers and their managers running a route with 2 dustcarts and 2 regular buses. It will be performed in Barcelona and the San Sebastián area of Spain. The professional drivers involved in UCC work full time as city bus drivers and/or garbage truck drivers respectively.

The focus of this group in the PANACEA project is to develop and evaluate a system that integrates sensors used to detect and avoid driving under impairment. Concretely, sensors aimed to detect drugs/alcohol, fatigue and drowsiness signs while driving. Therefore, alcohol/ drug use, fatigue and sleepiness are of major interest, and the different countermeasures, as well, are relevant from strategical, tactical and operative levels.

Real-world pilot UCC-R

From here, it is necessary to differentiate the description of the site for professional drivers between those who drive a garbage truck (dustcart) and perform overnight service, those drivers who regularly perform round-trip intercity service during their work shifts and those who regularly perform long distance trips (much of the trip being made at night).

The different UCC pilot sites:

- The R1 site is an urban scenario in Barcelona with two garbage trucks (ie Trucks).
- The R2 site will be a long-distance bus journey between San Sebastián and Paris.
- The R3 site will be interurban bus travel between San Sebastián and Bilbao.

Research questions

The main research questions are listed in Table 6 of D6.2 and additional research questions can be found in Appendix III.

Participants

The main participants are professional drivers. There will be garbage truck drivers and bus/coach drivers participating in the study. The professional drivers work full time as city bus drivers and/or truck drivers respectively. In total, 4-5 garbage truck drivers, and 10-14 bus drivers will participate.

The garbage truck drivers (ieTruck drivers) normally work just the night shifting. In relation to the night worker, article 36 of the Statute indicates that night work is considered to be that which meets at least one of the following requirements: One who normally performs at night a part of not less than three hours of his daily work day. Those who are expected to be able to perform a part of not less than one-third of their annual working day during the night period. To classify a worker as a night worker, what is important is the work schedule, that is, in view of the annual work calendar it is foreseeable that the worker meets any of the requirements indicated above.

Vehicles

The Spanish pilot site consists of 2 garbage trucks and 2 middle-distance buses. The garbage truck is an Irizar ie Truck (Figure 33). Systems installed in vehicles will recollect the data from the CAN system, the cameras streams and the embedded systems.

Irizar ie Truck

Figure 33. *Irizar ieTruck*

The buses are Irizar i6s motor MAN **(**Figure 34**).** Systems installed in vehicles will recollect the data from the CAN system, the cameras streams and the embedded systems. Data acquisition Datik Computing Brain (DCB) HW will be used.

[Irizar i6s integral bus]

Figure 34. *Irizar i6s bus*

Environment

The test sites will be different between those who drive a garbage truck and perform overnight service and those drivers who regularly perform round-trip intercity bus service during their work shifts. This is the UCC different pilot sites description:

SITE	VEHICLE	DRIVER	ITINERARY	SCHEDULE	Kms
R1	ieTruck	Professional driver	From garage - urban - unloading point – urban - garage	From 21 to 4	75/100 kms
R2	Irizar i6s - MAN	Professional driver	Garage - Donosti - Bilbao (relief) garage	Morning shift 5:30/6/6:30 (depends) Afternoon shift 12:30/13/13:30 (depends)	450 kms
R3	Irizar i6s	Professional driver	Garage - Donosti - París - garage	8 hours shift Morning shift starting at 5:30	420 kms

In the **UCC-R1** trial, the ieTrucks are used in a Barcelona garbage truck service. During the night shift, dustcart drivers complete an urban route with continuous stops (every 4-6 minutes) that carry out maneuvers to empty the containers. During this service, drivers are scheduled for at least one long trip to waste areas to empty the truck and continue service.

The **UCC-R2** trials are performed on a long journeys bus service (Apaolaza) from Donosti (San Sebastián) to París (Figure 35). The itinerary of the line would be: 09:30 departure from San Sebastián to Paris and the next day at 08:30 departure from Paris back to San Sebastián (daily from July 1 to September 4, after September night shift will be again considered)

This service would have 8 drivers who take turns, there are 4 groups of two drivers in each group. There are two fixed groups that work four days in a row and then rest two, these two days are complemented by another group of two drivers.

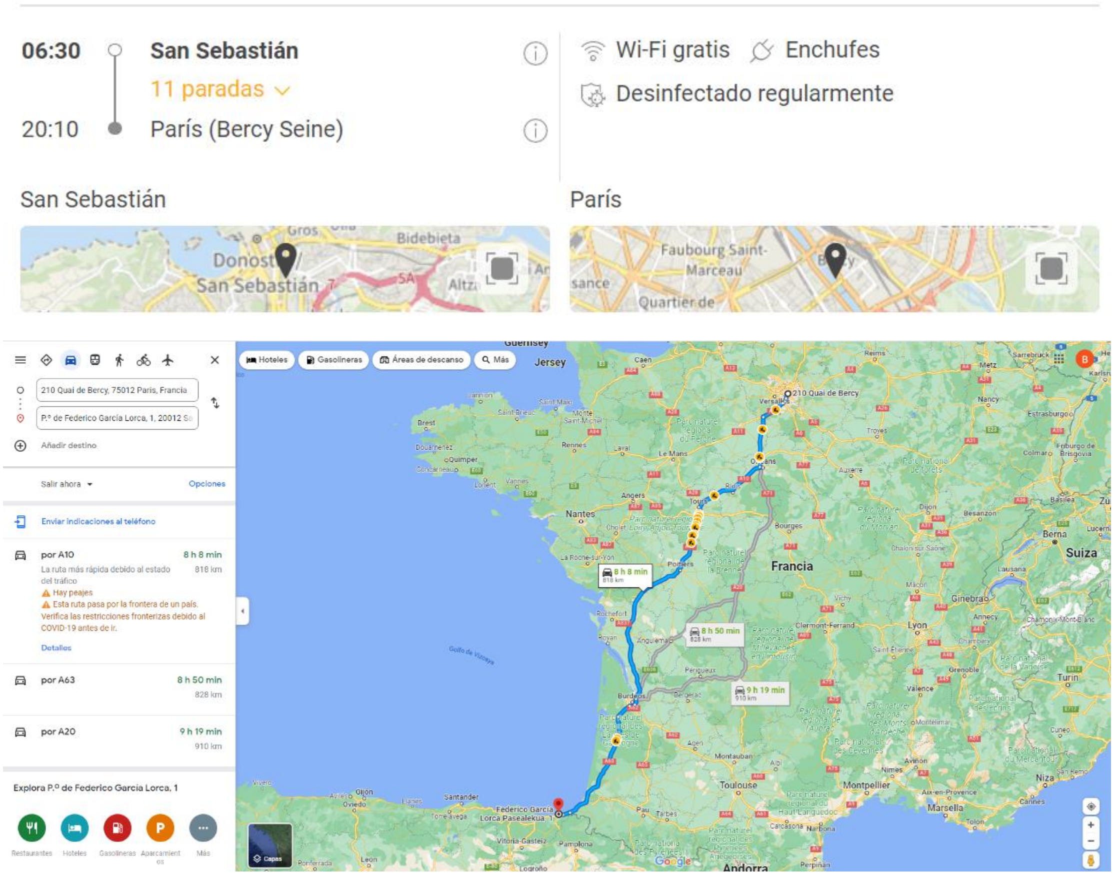
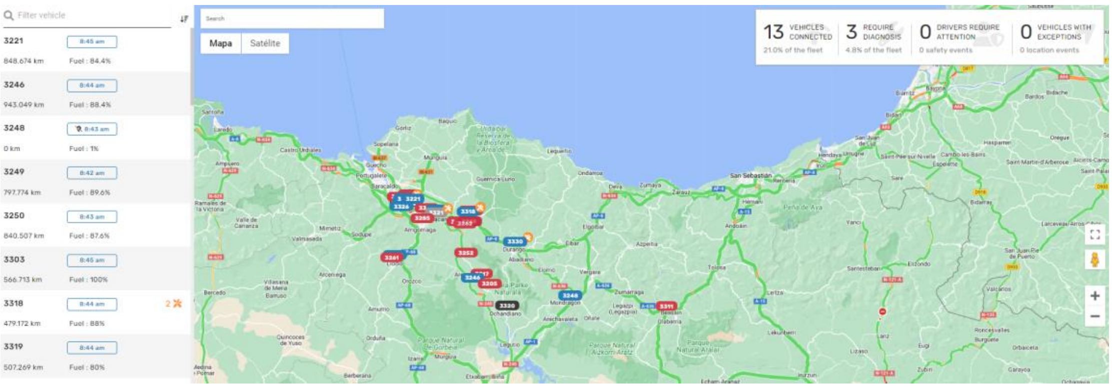


Figure 35. *Route from San Sebastián to Paris.*

The **UCC-R3** trips that Apaolaza drivers will perform are during the day. The bus service from Donosti (San Sebastián) to Bilbao leaves every half hour from 6 a.m. to 10 p.m. Each service is 1 hour and 15 minutes (Figure 36). The drivers' shifts start and end depending on the first service assignment. That is, there will be a group of drivers who will start a morning shift at 5:30, time enough to start the first journey service.

The vehicle in which Datik system will be installed will have characteristics similar to those of the vehicle presented below from which we already obtain location data from iPanel.



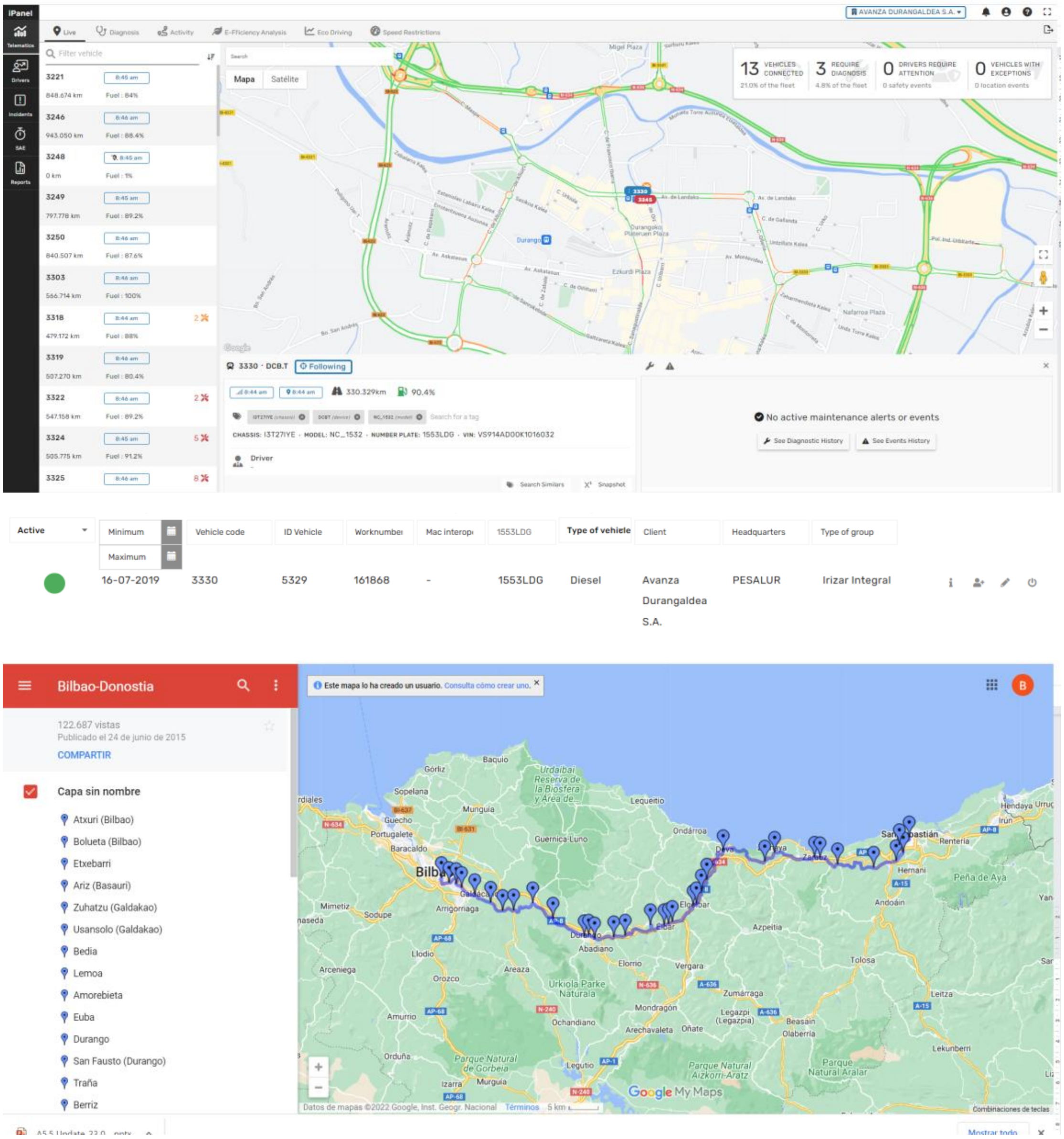


Figure 36. *Bus service from San Sebastián to Bilbao*

- Shifts of the drivers who perform this regular service (morning/afternoon/night)

Morning shifts: with start time between 5:00 a.m. and 8:00 a.m. and end time between 12:00 p.m. and 3:00 p.m.

Afternoon shifts: with start time between 1:00 p.m. and 6:00 p.m. and end time between 8:50 p.m. and 1:15 a.m.

- How many times does a driver make the Donosti-Bilbao route on their daily shift?

A maximum of two routes between Donosti and Bilbao and another two between Bilbao and Donosti

- Throughout the week, how many times?

In the week there are a maximum of 12 routes between Donosti and Bilbao and another 12 between Bilbao and Donosti

- Rests between the round trip from Donosti to Bilbo and if there is any extra rest.

Between the arrival time and the departure of the next journey there is always a lapse of 15 minutes. In all the graphs there is also a break that, depending on the graph, ranges between 45 minutes and two hours.

Driver impairments

The focus on driver impairments in Spain site are: alcohol/drug use, fatigue and stress detection.

Countermeasures

For UCC drivers the selection of countermeasures defined in A5.2 are shown in Table 22 and the countermeasures directed at operators are shown in

Table **23**.

Table 22. *Suggested PANACEA countermeasures for raising awareness of sleepiness / sleepiness advice*

Operational	Tactical	Strategic
-Strategies to manage sleepiness on shift (caffeine and napping)	-Advice on understanding sleepiness, recognising signs, effective countermeasures -Address accompanying fatigue contributors in workplace (scheduling, rest breaks etc.) -Offer education at all levels, tailored to co. -Training managers to identify sleepiness in drivers -Promoting adequate sleep between shifts	-Establishing an open culture/safety culture -Recurrent training -Lifestyle coaching for driver sleepiness

Table 23. *Suggested PANACEA countermeasures for optimising rest to reduce stress and fatigue*

Operational	Tactical	Strategic
-Fit-for-duty assessment	-Recommendations on good rest scheduling practices	-Alertness informed scheduling
-Alarm and feedback on driver states with holistic coaching on improvement		

Study design

The study design will be the same for all three driver groups (R1, R2, and R3). Approximately a total of 15-20 drivers counting the 3 demonstrators and sites.

A baseline assessment is planned where 1-month will be spent gathering information without the Datik system display so drivers cannot have access to the information being registered. The information will be displayed on iPanel but no feedback to drivers is supposed to be done. The AIT system will be registering data as well but without the stress countermeasure (balloons game) active. Senseair GO sensor will work as usual. ViF will be integrated with the Datik system so no feedback seems to be possible for the baseline assessment. The Leitat system on baseline will not be necessary.

After this first-period, data coming from the Datik system will be analysed and changes will be implemented (remotely) depending on the results. Thereafter, final evaluations will be done for 2 months with all sensors functioning as expected.

Each driver will do the PANACEA test at least 60 times in three months. The certain period for testing will be 3 months (1-month baseline and 2 months working properly, i.e., with all sensors and displays and countermeasures).

Data gathering tools

PANACEA sensors

The PANACEA technologies used in all three data collections are DATIK FitDrive and questionnaire, ViF Driver Monitoring System, AIT Smart PWA, Senseair Wall and Go, and Leitat biosensor.

Other objective data gathering tools

Data acquisition Datik Computing Brain (DCB) HW will be used. It will recollect the data from the CAN system, the cameras streams and the embedded systems.

DCB: this HW will function as a DataLogger and the information will be sent to the iPanel Cloud system.

- CAN data stream from vehicle
    - Speed
    - DriverID
- DSM Camera from FitDrive
    - MicroSleep
    - Yawning
    - Distraction
    - Phone call
    - …
- ADAS Camera from FitDrive
    - Lane Departure Warning
    - Front Collision Warning
    - …

Questionnaires

Drivers and operators will complete the respective background questionnaire before the baseline period. After the study the participants will be asked to answer a specific survey with question on acceptance, satisfaction and usability in relation to the system they just perceived. The questionnaire also includes follow-up questions on sleep problems, stress symptoms, quality of life that can be compared with the baseline questionnaire. This will be completed once in the end of the pilot.

Focus groups

Focus groups with stakeholders will be performed after the final evaluation. The evaluation of longer-term countermeasures and training content will be performed in dedicated focus groups with both bus drivers and operators/mangers.

Data analysis plan

Analyse the outputs from VIF, AIT and Datik system to obtain correlation factors between systems and adjust the events relevancy on the fatigue model.

Analyse potential differences between urban scenario and long trips use case.

Analyse the minimum sensors needed for having high precision on the prediction of the risk level.

Analyse the interface between the system and the drivers for adjusting the visual and sound alarms.

Analyze the age factor in the risk value assessment and evaluate the creation of different risk factor models depending on this variable.

Time Schedule

The baseline data collection will start in beginning of March2023 and the PANACEA data collection will occur during spring 2023.

Experimental plan Roadside study

The Roadside study is focused on test of two impairment sensors; LEITAT sensor for drugs (benzodiazepanes) and SENSEAIR GO Portable sensor for alcohol. The sensor will be tested among ordinary drivers in Norway by police officers from the Norwegian National Road Policing Service during autumn 2022 and spring 2023. The roadside assessments will study the reliability of the sensors and the practical use of the devices.

Roadside assessment

Research questions

How is the performance of the LEITAT sensor compared to the commercial drug sensor used by the Police in Norway?

How is the performance of the SENSEAIR Go Portable compared to the commercial alcohol sensor used by the Police in Norway?

How is the performance of the LEITAT sensor compared to the blood tests used by the Police in Norway?

Is the LEITAT/SENSEAIR Go Portable sensor usable (reliable and easy to use) in roadside assessments?

Participants

Police officers from the Norwegian National Road Policing Service and ordinary volunteer drivers in Norway.

Environment

Ordinary public road traffic in Norway.

Driver impairments

Alcohol and drug use. The reliability and the practical use of the devices will be tested among Norwegian drivers.

Countermeasures

In PANACEA, operational, tactical and strategic countermeasures are defined in relation to the work shift and described in Table 24.

Table 24. *PANACEA countermeasures levels*

	Operational	Tactical	Strategic
Time frame from impairment that countermeasure is deployed	Short-term – occurring during the shift when impairment is detected	Mid-term – soon after but not during the shift impairment is detected	Long-term - requiring ongoing engagement for prolonged period after the shift impairment is detected

There were two distinct stages in the methodology for the selection and development of countermeasures. The first was the identification of operational, tactical and strategic countermeasures which resulted in a shortlist of countermeasures per target user (driver, operator and enforcement) (A5.1). The second was a final selection of countermeasures and the development of their content that took place in A5.2 (Driver), A5.3 (Operator) and A5.4 (Enforcement).

- Four countermeasures were aimed at enforcement: Roadside assessment – Drugs (Operational), Roadside assessment – Alcohol (operational), Training of enforcement officers – Drugs (Tactical), Training of enforcement officers – Alcohol (Tactical).

The enforcer countermeasures have been passed to A5.5 for inclusion in the cloud-based system. The remainder of WP5 will focus on the development of this system.

Study design

The objective is to collect data to be used to check for level of agreement between LEITAT's and SENSEAIR's devices and the commercial devices currently in use by the Norwegian Police for roadside assessment.

Procedure for data collection

The Step-by-step action of Roadside Assessment Alcohol

- Police stops the driver
- Driver breaths into the Police’s own alcohol sensor *(Dräger 6820, Dräger 6810)*
- Driver is asked if he/she agrees to participate in testing a new device which entail to breath into the SENSEAIR GO portable device.
- Driver breath into SENSEAIR's device according to SENSEAIR manual.
- Result from SENSEAIR's device is presented to the Police, but result shall not be presented to the drivers.
- Police will read the results from their own sensors and decide how to proceed based on the results from their commercial devices, if the result is positive above legal limit a evidential breath-test or a blood sample will be needed.
- Police will send the results from the SENSEAIR sensor, the Police's alcohol sensor and if available, the corresponding results from evidential breath- or blood-sample to the PANACEA system for comparison

.

Figure 37. *Alcohol sensor currently in use by Norwegian police, Dräger 6820 and Dräger 6810*

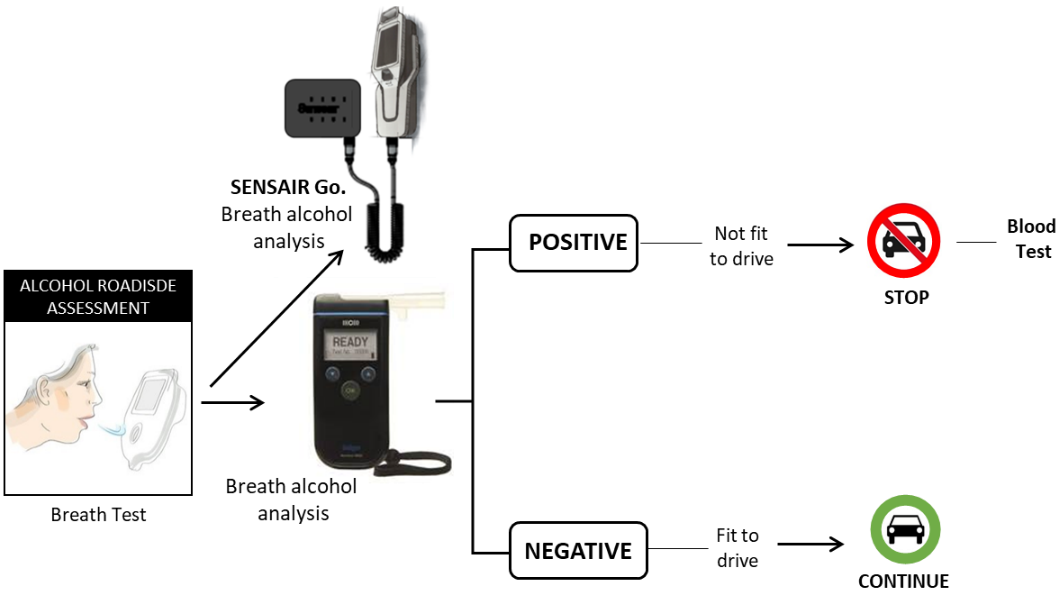


Figure 38. *Alcohol roadside assessment in Norway*

Figure 39. *SENSEAIR GO Portable alcohol sensor*

Figure 40. *User manual from SENSEAIR*

In case of grounds to believe of driving under influence of illicit/licit drugs Police collect saliva according to standard procedure using police's own device.

The Step-by-step action of Roadside Assessment Drug

- Police stops the driver
- Driver breaths into the Police's alcohol sensor
- In case of grounds to believe of driving under influence of illicit/licit drugs Police collect saliva according to standard procedure using police's own device (Dräger DrugTest5000 or Securetec´s WipeAlyser in combination with DrugWipe®).
- Drivers is asked if he/she agrees to participate in testing a new device which entail collecting an additional saliva sample.
- If the driver agrees to participate, police collect saliva according to LEITAT manual.
- Sample is processed directly in the LEITAT's device. Result from the LEITAT's device is presented to the Police, but result shall not be presented to the drivers.
- Police will read the results from their own sensors and decide how to proceed based on the results from their commercial devices if positive a blood sample might be needed.
- Police will send the results from the LEITAT's sensor, the Police device and if available, the corresponding results from evidential blood-sample to the PANACEA system for comparison.

Figure 41. *Dräger DrugTest5000[1] and Securetec´s WipeAlyser® with DrugWipe®[2]*

Both devices in use by Norwegian police for detection of drugs detect six different drugs:

- Opioids (codeine, ethyl morphine, heroin, morphine, oxycodone)
- Amphetamine/Methamphetamine (ecstasy, MDA, MDE/MDEA, MDMA)
- Cocaine (benzoylecgonine)
- Benzodiazepines (23 different substances; diazepam, clonazepam, oxazepam)
- Cannabis (cannabinol, delta 9 THC)

1 https://www.draeger.com/no_no/Products/DrugTest-5000

2 https://www.securetec.net/en/drug-test/

DrugWipe/WipeAlyser do not detect methadone. Dräger DrugTest5000 detect methadone with a cut-off of 20 ng/ml.

Testing will be done among volunteer drivers in ordinary public road traffic in Norway, in the area around Oslo, both among city traffic and on country roads.

Testing will be done according to knowledge-based alcohol-drug controls of the traffic police in Norway.

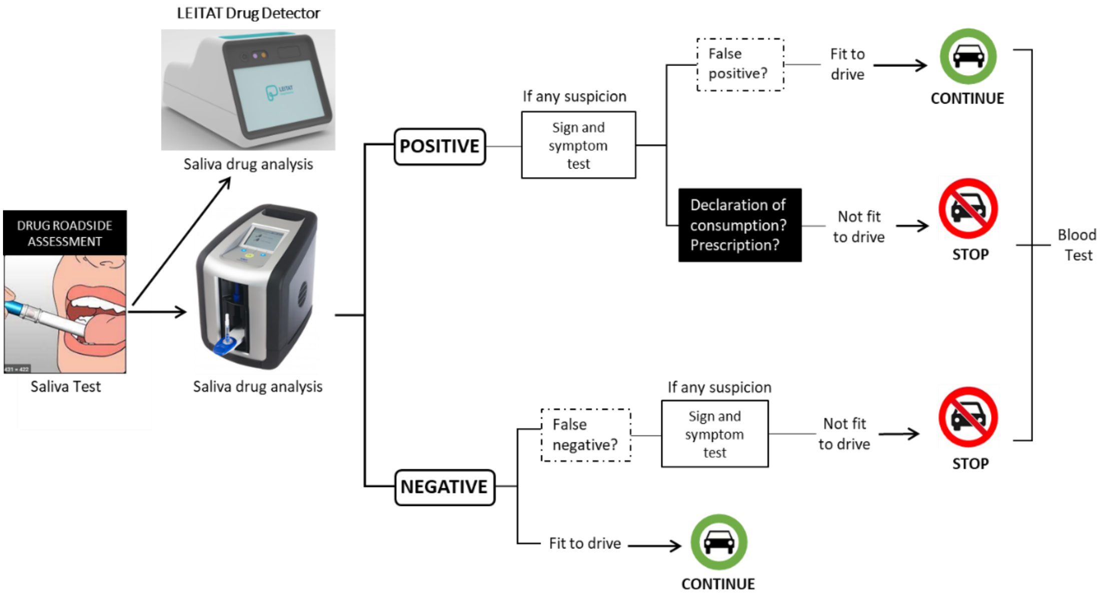


Figure 42. *Drug roadside assessment in Norway*

Figure 43. *LEITAT drug detector*

Figure 44. *User manual from LEITAT*

Data gathering tools

PANACEA sensors

SENSEAIR Go, LEITAT drug detector.

Reference equipment

Dräger 6820 and Dräger 6810 for BrAc and Dräger DrugTest5000 or Securetec´s WipeAlyser in combination with DrugWipe® for benzodiazepines and the blood test results used by the Police in Norway.

Other objective data gathering tools

The following information will be collected and reported to PANACEA SharePoint as an excel file, e.g.:

- Day and time
- Temperature
- Positive/Negative test on LEITAT and Senseair devices vs the Norwegian screening devices

- Evidential blood sample
- Experience of using the sensor (driver).
- Experience of using the sensor (police officer)

Questionnaires

Questionnaire to drivers with three questions about the experience of the sensors.

The drivers were asked the following questions:

Which instrument do you consider the easiest to blow in?

Which instrument do you consider to be the most time efficient?

Which instrument do you prefer to be tested with (total assessment)?

The response options were: 1=the instrument normally used by the police (Dräger), 2=equal, 3=PANACEA sensor (Senseair or Leitat sensor)

Questionnaire to police officers with questions about the experience of the sensors.

The police officers were asked about their age, gender, and number of years in the police. They were given the following questions about the sensors:

How would you rate the PANACEA test instrument (Senseair Portable GO or Leitat biosensor) compared to the instrument you normally use (Dräger breathalyzer (6820 or 6810) or Dräger drug sensor) in terms of the following factors (check):

	Better	Equal	Worse
Speed, the whole test procedure			
Hygiene			
Intrusion into the personal space of the driver			
Readability from the display in all weather/light conditions			
Intuitive use			
Size and design adapted to mobile (field) use			

The police officers also answered the SHAPE Automation Trust Index (SATI).

	never					always
1)…the system was useful.	0	1	2	3	4	5	6

	never						always
2)…the system was reliable.	0	1	2	3	4	5	6

	never					always
3)…the system worked accurately.	0	1	2	3	4	5	6

	never					always
4)…the system was understandable.	0	1	2	3	4	5	6

	never					always
5)…the system worked robustly (in difficult situations, with invalid inputs, etc.).	0	1	2	3	4	5	6

	never					always
6)…I was confident when working with the system.	0	1	2	3	4	5	6

Focus group with police officers after completion of the roadside testing.

Time plan

The roadside study for alcohol (SENSEAIR GO Portable) is planned for two a half months. Scheduled start-up 13th October 2022.

The roadside study for alcohol will primarily test among ordinary public road-users, with a planned minimum of 600 tests with at least 31 positive tests.

LEITAT drug detector is expected to be ready in the beginning of 2023. The roadside assessment is planned for Spring 2023 when the temperature in Norway is acceptable according to the LEITAT device requirements.

The roadside study for drug will aim for a minimum of 100 samples, including both positive and negative results. With a target of reaching 11 positive tests for Benzodiazepines. The test-period is anticipated for one month. Scheduled for March 2023[3].

3 Blood results ready after one month.

Appendix III Research Questions

RQ-category	Specific RQ	KPI (tentative)	Data gathering tool	UC	Data collection
Technical validation	**Do the PANACEA sensors/systems detect targeted driver impairments effectively with high sensitivity and specificity?**	KPI 2.1 Reliability of CHT, 2.2 Specificity of CHT, 2.3 Sensitivity of CHT, 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from sensors, subjective ratings of impairment	All (not all sensors in all UC)	All (not all sensors in all data collections)
Technical validation	**How is the performance of the PANACEA sensors compared to a reference measurement?**	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from PANACEA sensors & reference equipment	All	Simulator and roadside studies
Technical validation	How is the performance of the LEITAT sensor compared to the commercial drug sensor used by the Police in Norway?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from Leitat sensor & reference equipment	All	Roadside
Technical validation	How is the performance of the SENSEAIR Go Portable compared to the commercial alcohol sensor used by the Police in Norway?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from Senseair sensor & reference equipment	All	Roadside
Technical validation	How is the performance of the LEITAT sensor compared to the blood tests used by the Police in Norway?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Leitat sensor and blood test	All	Roadside
Technical validation	Does the sleep/wake history (24h data) in combination with a BMM give the same information compared to the subjective before-driving rating used by Datik?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from fitbit, BMM, & Datik	UCA	UCA real-world data collection

RQ-category	Specific RQ	KPI (tentative)	Data gathering tool	UC	Data collection
Technical validation	How do the measurements of the DATIK system and Optalert match?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from Datik and Optalert	UCB	UCB CERTH simulator study
Technical validation	How do the measurement of SENSEAIR and BACtrack skyn match?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from Senseair and BACtrack sensors	UCB	UCB CERTH simulator study
Technical validation	Does the AIT Pulse Wave Analysis (PWA) device and Galvanic Skin Response (GSR) sensors' measurements match?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from PWA and GSR sensors	UCB	UCB CERTH simulator study
Technical validation	Will addressed levels of driver state and/ or impairment be captured?	KPI 2.1 Reliability of CHT, 2.2 Specificity of CHT, 2.3 Sensitivity of CHT	Data from sensors, subjective ratings of impairment	UCB	UCB CERTH simulator study
Technical validation	What sensor data are the best driver state behaviour impairment indicators?	KPI 2.1 Reliability of CHT, 2.2 Specificity of CHT, 2.3 Sensitivity of CHT	Data from sensors	UCB	UCB ViF simulator study
Sensor fusion	Which combination of algorithms can best capture impaired driving in the respective environment?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from sensors	UCB	UCB ViF simulator study
Technical validation	What are the critical differences in detecting impaired driving in city traffic versus motorway / country road traffic?	KPI 2.1 Reliability of CHT, 2.2 Specificity of CHT, 2.3 Sensitivity of CHT	Data from sensors	UCB	UCB ViF simulator study
Effectiveness and operability	Is the LEITAT/SENSEAIR Go Portable sensor reliable and easy to use in roadside assessments?	KPI 3.1 Ease to use CHT, 3.2 Usefulness of CHT, 3.3 Willingness to use CHT	Questionnaires	All	Roadside

RQ-category	Specific RQ	KPI (tentative)	Data gathering tool	UC	Data collection
Sensor fusion	**Do the combined sensors improve driver state detection?**	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from PANACEA sensors (individual and combined)	All	All real-world data collections ?
Sensor fusion	Can sleep/wake history (24h data) in combination with a BMM be used to distinguish different types of fatigue (and thus give more accurate countermeasures)?	KPI 2.4 Sensitivity and specificity of a sensor or combination of technologies	Data from fitbit, BMM and subjective ratings of fatigue	UCA	UCA real-world data collection
Validation of the integrated system in real life	**Does the PANACEA integrated solution work in a real-life setting to detect impairment and deliver counter measures?**	KP 1.2 Technical performance of CHT, KPI 2.1 Reliability of CHT, 2.2 Specificity of CHT, 2.3 Sensitivity of CHT	Data from PANACEA solution and subjective ratings of impairment	All	All real-world data collections
Validation of the integrated system in real life	Is it possible to get around using highly specific baseline/calibration recordings and still get accurate estimates of driver state?	KPI 1.2 Technical performance of CHT	Data from sensors	UCB	UCB real-world data collection
Acceptance	**Are the PANACEA sensors/systems accepted by the users?**	KPI 3.4 Acceptance of CHT	Questionnaires	All	All real-world data collections
Usability	**Are the CHTs perceived as useful, satisfying, trustworthy, and easy to use?**	KPI 3.1 Ease to use CHT, 3.2 Usefulness of CHT, 3.3 Willingness to use CHT	Questionnaires	All	All real-world data collections
Acceptance	How willing are the participants to use wearable devices 24h a day? What is the data availability after an extended period (several months) of usage? Is it too intrusive?	KPI 3.1 Ease to use CHT, 3.2 Usefulness of CHT, 3.3 Willingness to use CHT, 3.5 Trust in CHT, , 3.6 Satisfaction of CHT	Questionnaires and focus groups	All	All real-world data collections

RQ-category	Specific RQ	KPI (tentative)	Data gathering tool	UC	Data collection
Willingness to use	Why do drivers not engage with the CHT if they don't engage?	KPI 3.3 Willingness to use CHT, 3.6 Satisfaction of CHT	Focus group	All	All real-world data collections
Effectiveness of the countermeasure	**What are the immediate effects of implemented countermeasures?**	KPI 4.3 Effectiveness of a countermeasure	Questionnaires/Data from PANACEA system	All	All real-world data collections
Effectiveness of the countermeasure	Will the 24h data reveal poor sleep hygiene, and if so, is it possible to fix with the Panacea countermeasures?	KPI 4.3 Effectiveness of a countermeasure	Data from fitbit and PANACEA system	UCA	UCA real-world data collection
Effectiveness of the countermeasure	From iCloud System data is it possible to measure the effects (short-term and lifestyle) of an implemented countermeasure?	KPI 4.3 Effectiveness of a countermeasure	Data from PANACEA solution	All	All real-world data collections
Effectiveness of the countermeasure	Is the AIT system sensor effective as a countermeasure for stress?	KPI 4.3 Effectiveness of a countermeasure		UCB, UCC	UCB & UCC real-world data collection
Acceptance	Does the countermeasures for sleep related fatigue (while driving) work in a professional setting with tight schedules?	KPI 4.2 Acceptance of a countermeasure, 4.5 Willingness to use a countermeasure	Questionnaire	All	All real-world data collections
Acceptance	Are drivers willing to sacrifice their breaks to do scheduled measurements and relaxations tasks?	KPI 4.2 Acceptance of a countermeasure, 4.5 Willingness to use a countermeasure	Questionnaire	All	All real-world data collections
Acceptance	**Is the PANACEA countermeasures system accepted by the users?**	KPI 4.2 Acceptance of a countermeasure, 4.5 Willingness to use a countermeasure	Questionnaire	All	All real-world data collections
Acceptance	To what extent do drivers/operators engage with the countermeasures	KPI 4.2 Acceptance of a countermeasure	Usage data from PANACEA system	All	All real-world data collections

RQ-category	Specific RQ	KPI (tentative)	Data gathering tool	UC	Data collection
	delivered by the cloud based system				
Willingness to use	Why do drivers not engage with the countermeasure if they don't engage?	KPI 4.5 Willingness to use a countermeasure	Focus group	All	All real-world data collections
Impact of countermeasures	**Does behaviour change/improve after the relevant countermeasure has been administered?**	KPI 4.3 Effectiveness of a countermeasure, KPI 7.4 CEA ratio or CBA ratio	Questionnaires/Data from PANACEA system	All	All real-world data collections
Impact of countermeasures	**Will the PANACEA countermeasures reduce driver impairment and improve the driver performance?**	KPI 7.3 N of saved lives, 7.5 QoL?	Questionnaires/Data from PANACEA system/driving performance data from vehicles	All	All real-world data collections
Long-term usage (business case)	**Would it be possible to implement the PANACEA system in regular operation?**	KPI 7.4 CEA ratio or CBA ratio	Focus group with different stakeholders	All	All real-world data collections
Safety	**Does the PANACEA system increase perceived (drivers) and reported (operators) safety?**	KPI 1.1 Perceived (drivers) safety, KPI 1.2, Reported (operators) safety	Questionnaire & focus group (& data from PANACEA solution?)	All	All real-world data collections
Study-specific RQ	Can fatigue prediction using BMM be improved by taking next-day effects of alcohol consumption into account?		Data from sensors, subjective ratings of impairment	UCA	UCA simulator study
Study-specific RQ	How does moderate alcohol intake in the evening affect night sleep and next day driving performance?		Data from sensors, simulator data, subjective ratings of impairment	UCA	UCA simulator study
Study-specific RQ	How do fatigue levels change across the working shift?		Data from sensors, subjective ratings of impairment	UCB	UCB CERTH simulator study
Study-specific RQ	How do stress levels change across the shift?		Data from sensors, subjective ratings of impairment	UCB	UCB CERTH simulator study

Appendix IV Questionnaires

Background questionnaire for drivers

To be completed before using the PANACEA system.

PANACEA participant ID__________________

How long have you been working as a bus driver/delivery rider/garbage truck driver/taxi driver? ________________ years.

How much do you work as a driver/delivery rider/garbage truck driver/taxi driver?

☐ Full time

☐ Part time

I work on average ______________ h per week.

Which of the following do you use to get to work?

☐ Walk

☐ Cycle

☐ Car

☐ Public transport

☐ Other

How long does it take you to get to work from home? _____________ min

When do you usually work?

☐ Daytime, evening, and weekends

☐ Daytime, evening, nights, and weekends

☐ Only nights

☐ Daytime Monday to Friday (occasional evenings)

☐ Other

How long have you had a driver's license (for passenger car)? _____________ years.

How many kilometers do you usually drive in a week?

On duty ________ km

Off duty ________ km

What is your highest level of education?

☐ Primary/Elementary school

☐ Secondary/High school degree

☐ Trade or technical training

☐ University or college degree

Do you have any previous experience with the following?

	Yes, some	**Yes, a lot**	**No**	**Don't know**
In-vehicle fatigue warning	☐	☐	☐	☐
In-vehicle alcolock	☐	☐	☐	☐
Alcolock at a depot or garage	☐	☐	☐	☐
Activity wrist band	☐	☐	☐	☐
Sleep tracker	☐	☐	☐	☐
Stress sensor	☐	☐	☐	☐
Coaching or aid/countermeasure to reduce fatigue	☐	☐	☐	☐

Coaching or aid/countermeasure to reduce stress	☐	☐	☐	☐
Coaching or aid/countermeasure to reduce alcohol consumption	☐	☐	☐	☐
Coaching or aid/countermeasure to reduce drug use	☐	☐	☐	☐
	☐	☐	☐	☐

In the past month, have you had a ‘close call’ on the road while you were working?

☐ Never

☐ Once

☐ Twice

☐ Three times or more

In the past month, have you had a ‘close call’ on the road while you were <u>not</u> working?

☐ Never

☐ Once

☐ Twice

☐ Three times or more

In the past 12 months, have you been involved in a road crash?

☐ Never

☐ Once

☐ Twice

☐ Three times or more

Over the last 30 days, how often did you …?

	Never 1	2	3	4	Almost always 5
Drive when you may have been over the legal limit for drinking and driving					
Drive after drinking alcohol					
Drive 1 hour after using drugs (other than medication)					
Drive after taking medication that carries a warning that it may influence your driving ability					
Talk on a hand-held mobile phone while driving					
Talk on a hands-free mobile phone while driving					
Read a text message/email or check social media (e.g. Facebook, twitter, etc.) while driving					
Drive when you were so sleepy that you had trouble keeping your eyes open					

How much do you think the following impacts your driving safety when at work?

	Not at all	Just a little	To some extent	Rather much	Very much
Sleepiness					
Stress					
Alcohol use					
Drug use					
Distraction or inattention					

Questions about sleep

How many hours do you usually sleep per 24 hour period? _____________h

How much sleep do you need per 24 hour to feel alert in the day? ____________h

1. Are you getting enough sleep?

☐ Yes, definitely

☐ Yes, more or less

☐ No, slightly to little

☐ No, not enough

☐ No, far from enough

2. In general how would you like to rate your sleep?

☐ Very good

☐ Rather good

☐ Neither good nor bad

☐ Rather bad

☐ Very bad

BOSS (Bourdeaux Sleepiness Scale)

1. Gender

☐ Female

☐ Male

2. Number of km driven per year:______________ km/year

☐ Less than 20000 km/year

☐ Equal to or more than 20000 km/year

3. Recently, how likely are you to doze off or fall asleep in contrast to feeling just tired in a car while stopped for a few minutes in traffic

☐ Would never doze

☐ Slight chance of dozing

☐ Moderate chance of dozing

☐ High chance of dozing

4. Have you experienced in the previous year at least one episode of severe sleepiness at the wheel that made driving difficult or forced you to stop the car?

☐ No, never

☐ Yes, but less than once a month

☐ Yes, at least once a month

☐ Yes, at least once a week

Question about stress symptoms

Stress means a situation in which a person feels tense, restless, nervous or anxious or is unable to sleep at night because his/her mind is troubled all the time. Do you feel this kind of stress these days?

- ☐ Not at all
- ☐ Just a little
- ☐ To some extent
- ☐ Rather much
- ☐ Very much

Alcohol use

AUDIT *(english)*

Below you will find a few questions concerning your drinking habits during the past year.

Please mark the alternative that applies to you. Thank you for answering the questions as accurately and honestly as possible.

One "standard drink"

HOW OLD ARE YOU? _______ ❑ MALE ❑ FEMALE

1. How often do you have a drink containing alcohol?	NEVER ❑	MONTHLY OR LESS ❑	2–4 TIMES A MONTH ❑	2–3 TIMES A WEEK ❑	4 OR MORE TIMES A WEEK ❑
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1–2 ❑	3–4 ❑	5–6 ❑	7–9 ❑	10 OR MORE ❑
3. How often do you have six or more drinks on one occasion?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
4. How often during the last year have you found that you were not able to stop drinking once you had started?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
9. Have you or someone else been inju-red as a result of your drinking?	NO ❑		YES, BUT NOT IN THE LASTYEAR ❑		YES, DURING THE LAST YEAR ❑
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	NO ❑		YES, BUT NOT IN THE LASTYEAR ❑		YES, DURING THE LAST YEAR ❑

Drug use

Have you been using drugs the last month (e.g. marijuana, hash, ecstasy)?

o No	o Yes, once	o Yes, several times	o Do not remember

Do you take any prescription medicine?

o No	o Yes, Sometimes	o Yes, on regular basis

Type of prescription medicine: ____

Quality of life

Health Questionnaire (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

☐1 I have no problems in walking about
☐2 I have slight problems in walking about
☐3 I have moderate problems in walking about
☐4 I have severe problems in walking about
☐5 I am unable to walk about

SELF-CARE

☐1 I have no problems washing or dressing myself
☐2 I have slight problems washing or dressing myself
☐3 I have moderate problems washing or dressing myself
☐4 I have severe problems washing or dressing myself
☐5 I am unable to wash or dress myself

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

☐1 I have no problems doing my usual activities
☐2 I have slight problems doing my usual activities
☐3 I have moderate problems doing my usual activities
☐4 I have severe problems doing my usual activities
☐5 I am unable to do my usual activities

PAIN / DISCOMFORT

☐1 I have no pain or discomfort
☐2 I have slight pain or discomfort
☐3 I have moderate pain or discomfort
☐4 I have severe pain or discomfort
☐5 I have extreme pain or discomfort

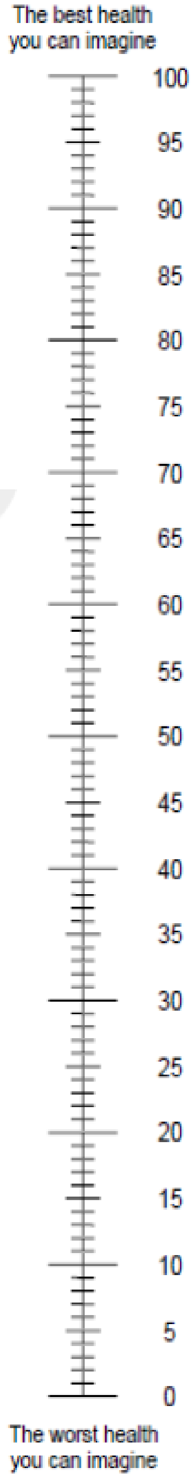
ANXIETY / DEPRESSION

☐1 I am not anxious or depressed
☐2 I am slightly anxious or depressed
☐3 I am moderately anxious or depressed
☐4 I am severely anxious or depressed
☐5 I am extremely anxious or depressed

Health Questionnaire (EQ-5D-5L)

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = [ ]



Background questionnaire for operators/managers

To be completed before using the PANACEA system.

PANACEA participant ID____________________

In the past month, have any of your employees had a 'close call' on the road while on duty?

- ☐ Never
- ☐ Once
- ☐ Twice
- ☐ Three times or more

In the past 12 months, have any of your employees been involved in a road crash while on duty?

- ☐ Never
- ☐ Once
- ☐ Twice
- ☐ Three times or more

Over the last 30 days, how many times have you been aware of employees doing the following while on duty?

	Never	**Once**	**Twice**	**Three times or more**	**Don't know**
Drive when they may have been over the legal limit for drinking and driving					
Drive after drinking alcohol					
Drive 1 hour after using drugs (other than medication)					

Drive after taking medication that carries a warning that it may influence their driving ability
Talk on a hand-held mobile phone while driving
Talk on a hands-free mobile phone while driving
Read a text message/email or check social media (e.g. Facebook, twitter, etc.) while driving
Drive when they were so sleepy that they had trouble keeping their eyes open

Do you have any previous experience with the following?

	Yes, some	Yes, a lot	No	Don't know
In-vehicle fatigue warning	5	5	5	5
In-vehicle alcolock	5	5	5	5
Alcolock at a depot or garage	5	5	5	5
Activity wrist band	5	5	5	5
Sleep tracker	5	5	5	5
Stress sensor	5	5	5	5
Coaching or aid/countermeasure to reduce fatigue	5	5	5	5
Coaching or aid/countermeasure to reduce stress	5	5	5	5
Coaching or aid/countermeasure to reduce alcohol consumption	5	5	5	5
Coaching or aid/countermeasure to reduce drug use	5	5	5	5

5	5	5	5	

How much do you think the following impacts your employees' driving safety when at work?

	Not at all	Just a little	To some extent	Rather much	Very much
Sleepiness					
Stress					
Alcohol use					
Drug use					
Distraction or inattention					

Daily evaluation questionnaire/diary for drivers

To be completed at the end of each work shift while using the PANACEA system.

PANACEA participant ID__________________

Self-reported sleepiness (KSS)
Rate your highest level of sleepiness during the working day.

1	Extremely alert
2	Very alert
3	Alert
4	Rather alert
5	Neither alert nor sleepy
6	Some signs of sleepiness
7	Sleepy, but no effort to keep awake
8	Sleepy, some effort to keep awake
9	Very sleepy, great effort to keep awake, fighting sleep

VTI Acute Stress Scale (VSS)
Rate your highest level of stress during the working day.

1	Completely relaxed (feeling entirely calm and relaxed)
2	Very relaxed
3	Relaxed
4	Rather relaxed
5	Neither relaxed nor stressed
6	Slightly stressed
7	Stressed (feeling some tension and pressure)
8	Very stressed
9	Extremely stressed (feeling very tense and under high pressure, on the verge of what I can handle)

Did you use alcohol in the 12h period before starting your shift?

☐ Yes ☐ No

Did you use drugs in the 12h period before starting your shift?

☐ Yes ☐ No

Did the PANACEA system work well?

☐ Yes ☐ No

Problems encountered: ___________________________________

Did the vehicle you drove/operated work well?

☐ Yes ☐ No

Problems encountered: ___________________________________

Did you get a fatigue warning while driving?

☐ Yes ☐ No

If so, was it relevant?

☐ Yes ☐ No

Were you fatigued but did not receive a warning?

☐ Yes ☐ No

Did you receive an invitation to fill in the fatigue questionnaire?

☐ Yes ☐ No

If so, was it relevant?

☐ Yes ☐ No

Evaluation questionnaire for drivers

To be completed after using the PANACEA system.

PANACEA participant ID__________________

In the past month, have you had a 'close call' on the road while you were working?

☐ Never

☐ Once

☐ Twice

☐ Three times or more

In the past month, have you had a 'close call' on the road while you were not working?

☐ Never

☐ Once

☐ Twice

☐ Three times or more

In the past 12 months, have you been involved in a road crash?

☐ Never

☐ Once

☐ Twice

☐ Three times or more

Over the last 30 days, how often did you…?

	Never 1	2	3	4	Almost always 5
Drive when you may have been over the legal limit for drinking and driving					
Drive after drinking alcohol					
Drive 1 hour after using drugs (other than medication)					
Drive after taking medication that carries a warning that it may influence your driving ability					
Talk on a hand-held mobile phone while driving					
Talk on a hands-free mobile phone while driving					
Read a text message/email or check social media (e.g. Facebook, twitter, etc.) while driving					
Drive when you were so sleepy that you had trouble keeping your eyes open					

How much do you think the following impacts your driving safety when at work?

	Not at all	Just a little	To some extent	Rather much	Very much
Sleepiness					
Stress					
Alcohol use					
Drug use					
Distraction or inattention					

Evaluation of the PANACEA system

What is your general opinion of the PANACEA system?

☐	☐	☐	☐	☐
Very positive	Somewhat positive	Neutral	Somewhat negative	Very negative

	Completely disagree				Completely agree
I would like to have this system at my workplace.	1	2	3	4	5
If I had access to PANACEA in the future, I would be willing to use it.	1	2	3	4	5
I think the PANACEA system would improve working conditions.	1	2	3	4	5
I think a system like PANACEA could be useful for other transport modes (i.e., air, maritime, rail).	1	2	3	4	5

Several aspects are listed in the following table. Please indicate how these aspects can change if you are a driver using the PANACEA system.

	Decrease	Stay the same	Increase
Safety	☐	☐	☐
Number of accidents	☐	☐	☐

Severity of accidents	☐	☐	☐
Attention towards the road	☐	☐	☐
Stress	☐	☐	☐
Fatigue	☐	☐	☐
Alcohol use	☐	☐	☐
Drug use	☐	☐	☐
Possibility to drive longer (longer trips)	☐	☐	☐
Possibility to drive longer (more years)	☐	☐	☐
Worry about system failure or data breach	☐	☐	☐
Feeling of being controlled	☐	☐	☐

Do you have any other comments about the PANACEA system?

___

___

___

___

___

Technology Acceptance Scale by van der Laan

My judgements of the PANACEA system are ... (please tick one box in every line)

Useful						Useless
Pleasant						Unpleasant
Bad						Good
Nice						Annoying
Effective						Superfluous
Irritating						Likeable
Assisting						Worthless
Undesirable						Desirable
Raising Alertness						Sleep-inducing

System Usability Scale (SUS)

	Strongly disagree				Strongly agree
I think that I would like to use this system frequently	1	2	3	4	5
I found the system unnecessarily complex	1	2	3	4	5
I thought the system was easy to use	1	2	3	4	5
I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
I found the various functions in this system were well integrated	1	2	3	4	5
I thought there was too much inconsistency in this system	1	2	3	4	5
I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
I found the system very cumbersome to use	1	2	3	4	5
I felt very confident using the system	1	2	3	4	5
I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

SHAPE Automation Trust Index (SATI)

	never						always
1)…the system was useful.	0	1	2	3	4	5	6

	never						always
2)…the system was reliable.	0	1	2	3	4	5	6

	never						always
3)…the system worked accurately.	0	1	2	3	4	5	6

	never						always
4)…the system was understandable.	0	1	2	3	4	5	6

	never						always
5)…the system worked robustly (in difficult situations, with invalid inputs, etc.).	0	1	2	3	4	5	6

	never						always
6)…I was confident when working with the system.	0	1	2	3	4	5	6

Questions about sleep

How many hours do you usually sleep per 24 hour period? _____________h

How much sleep do you need per 24 hour to feel alert in the day? ____________h

3. Are you getting enough sleep?

☐ Yes, definitely

☐ Yes, more or less

☐ No, slightly to little

☐ No, not enough

☐ No, far from enough

4. In general how would you like to rate your sleep?

☐ Very good

☐ Rather good

☐ Neither good nor bad

☐ Rather bad

☐ Very bad

BOSS (Bourdeaux Sleepiness Scale)

5. Gender

☐ Female

☐ Male

6. Number of km driven per year:______________ km/year

☐ Less than 20000 km/year

☐ Equal to or more than 20000 km/year

7. Recently, how likely are you to doze off or fall asleep in contrast to feeling just tired in a car while stopped for a few minutes in traffic

☐ Would never doze

☐ Slight chance of dozing

☐ Moderate chance of dozing

☐ High chance of dozing

8. Have you experienced in the previous year at least one episode of severe sleepiness at the wheel that made driving difficult or forced you to stop the car?

☐ No, never

☐ Yes, but less than once a month

☐ Yes, at least once a month

☐ Yes, at least once a week

Question about stress symptoms

Stress means a situation in which a person feels tense, restless, nervous or anxious or is unable to sleep at night because his/her mind is troubled all the time. Do you feel this kind of stress these days?

☐ Not at all

☐ Just a little

☐ To some extent

☐ Rather much

☐ Very much

Alcohol use

AUDIT *(english)*

Below you will find a few questions concerning your drinking habits during the past year.

Please mark the alternative that applies to you. Thank you for answering the questions as accurately and honestly as possible.

One "standard drink"

HOW OLD ARE YOU? ______ ❑ MALE ❑ FEMALE

1. How often do you have a drink containing alcohol?	NEVER ❑	MONTHLY OR LESS ❑	2–4 TIMES A MONTH ❑	2–3 TIMES A WEEK ❑	4 OR MORE TIMES A WEEK ❑
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1–2 ❑	3–4 ❑	5–6 ❑	7–9 ❑	10 OR MORE ❑
3. How often do you have six or more drinks on one occasion?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
4. How often during the last year have you found that you were not able to stop drinking once you had started?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	NEVER ❑	LESS THAN MONTHLY ❑	MONTHLY ❑	WEEKLY ❑	DAILY OR ALMOST DAILY ❑
9. Have you or someone else been injured as a result of your drinking?	NO ❑		YES, BUT NOT IN THE LASTYEAR ❑		YES, DURING THE LAST YEAR ❑
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	NO ❑		YES, BUT NOT IN THE LASTYEAR ❑		YES, DURING THE LAST YEAR ❑

Drug use

Have you been using drugs the last month (e.g. marijuana, hash, ecstasy)?

o No	o Yes, once	o Yes, several times	o Do not remember

Do you take any prescription medicine?

o No	o Yes, Sometimes	o Yes, on regular basis

Type of prescription medicine: ____

Quality of life

Health Questionnaire (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- ☐1 I have no problems in walking about
- ☐2 I have slight problems in walking about
- ☐3 I have moderate problems in walking about
- ☐4 I have severe problems in walking about
- ☐5 I am unable to walk about

SELF-CARE

- ☐1 I have no problems washing or dressing myself
- ☐2 I have slight problems washing or dressing myself
- ☐3 I have moderate problems washing or dressing myself
- ☐4 I have severe problems washing or dressing myself
- ☐5 I am unable to wash or dress myself

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- ☐1 I have no problems doing my usual activities
- ☐2 I have slight problems doing my usual activities
- ☐3 I have moderate problems doing my usual activities
- ☐4 I have severe problems doing my usual activities
- ☐5 I am unable to do my usual activities

PAIN / DISCOMFORT

- ☐1 I have no pain or discomfort
- ☐2 I have slight pain or discomfort
- ☐3 I have moderate pain or discomfort
- ☐4 I have severe pain or discomfort
- ☐5 I have extreme pain or discomfort

ANXIETY / DEPRESSION

- ☐1 I am not anxious or depressed
- ☐2 I am slightly anxious or depressed
- ☐3 I am moderately anxious or depressed
- ☐4 I am severely anxious or depressed
- ☐5 I am extremely anxious or depressed

Health Questionnaire (EQ-5D-5L)

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is **TODAY**
- Now, please write the number you marked on the scale in the

  below.

YOUR HEALTH TODAY =

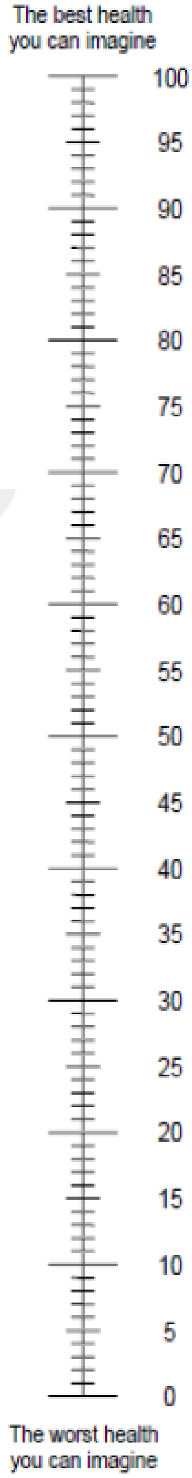


Table 25: *Caption of table. Table content should be aligned left (not justify). Caption above the table.*

Countermeasures' evaluation

Fatigue report evaluation

Did you at any point receive a Fatigue report?

☐ Yes ☐ No

	Completely disagree				Completely agree
The information in the fatigue report was easy to understand.	1	2	3	4	5
The fatigue reports were accurate.	1	2	3	4	5
The content of the fatigue reports was relevant.	1	2	3	4	5
The frequency of the reports was appropriate.	1	2	3	4	5
These reports have increased my awareness of how sleep is affecting my driving on shift.	1	2	3	4	5
The advice and information in the report was useful.	1	2	3	4	5
The safety of my driving has been improved by the fatigue report.	1	2	3	4	5

Have you actively tried to change your sleep/relaxation habits since receiving the reports?

☐ Yes ☐ No

In what way(s) have you been changing your sleep/relaxation habits? (set up a drop down list of options)

Did you submit your reports to the operator?

☐ Yes ☐ No

	Completely disagree				Completely agree
I was comfortable in submitting the fatigue reports to my operator.	1	2	3	4	5
Submitting the report to my operator has been beneficial to me.	1	2	3	4	5

Fatigue Questionnaire evaluation

Did you at any point receive a Fatigue Questionnaire?

☐ Yes ☐ No

	Completely disagree				Completely agree
The fatigue questionnaire and information provided was easy to understand.	1	2	3	4	5
The content of the fatigue questionnaire was relevant.	1	2	3	4	5
The frequency of the questionnaires was appropriate.	1	2	3	4	5
These questionnaires have increased my awareness of how sleep is affecting my driving on shift.	1	2	3	4	5
The tips at the end of the questionnaire were useful.	1	2	3	4	5
The safety of my driving has been improved by the fatigue questionnaire.	1	2	3	4	5

Have you actively tried to change your sleep/relaxation habits since receiving the fatigue questionnaire?

☐ Yes ☐ No

In what way(s) have you been changing your sleep/relaxation habits? (set up a drop down list of options)

Did you submit your questionnaire results to the operator?

☐ Yes ☐ No

	Completely disagree				Completely agree
I was comfortable in submitting the questionnaire results to my operator.	1	2	3	4	5
Submitting the results to my operator has been beneficial to me.	1	2	3	4	5

Stress management tool evaluation

Did you at any point receive a Stress management tool?

☐ Yes ☐ No

	Completely disagree				Completely agree
The stress management tool was easy to understand.	1	2	3	4	5
The balloon game was useful.	1	2	3	4	5
The self-relaxation time (with/without timer) was useful.	1	2	3	4	5
The stress management tool has increased my awareness of how stress is affecting my driving on shift.	1	2	3	4	5
My stress levels have changed since using the stress management tool.	1	2	3	4	5

The safety of my driving has been improved by the stress management tool.	1	2	3	4	5

Have you actively introduced stress management techniques into your daily routine since starting this trial?

☐ Yes ☐ No

Have you been taking more breaks since the stress management notifications have been introduced?

☐ Yes ☐ No

Did you follow the post-evaluation advice (good to go/wait a little longer)?

☐ Yes, always ☐ Yes, sometimes ☐ No

Coaching system evaluation

Thinking about the platform from which you received the countermeasure (insert the name of one of the 3 options) I found the use of the countermeasures system

Useful						Useless
Pleasant						Unpleasant
Bad						Good
Nice						Annoying
Effective						Superfluous

Irritating						Likeable
Assisting						Worthless
Undesirable						Desirable
Demotivating						Motivating

	Not at all				A lot
Since using PANACEA I have changed my behaviour to reduce fatigue	1	2	3	4	5
Since using PANACEA I have changed my behaviour to stress	1	2	3	4	5

If PANACEA included countermeasures to other impairments how willing would you be to use it for

	Not at all willing				Very willing
Alcohol	1	2	3	4	5
Illicit drugs	1	2	3	4	5
Cognitive distraction	1	2	3	4	5

I think the PANACEA countermeasures could be useful for other transport modes (i.e., air, maritime, rail).

Completely disagree	Completely agree

1	2	3	4	5

Evaluation questionnaire for operators/managers

To be completed after using the PANACEA system.

PANACEA participant ID_________________

In the past month, have any of your employees had a 'close call' on the road while on duty?

- ☐ Never
- ☐ Once
- ☐ Twice
- ☐ Three times or more

In the past 12 months, have any of your employees been involved in a road crash while on duty?

- ☐ Never
- ☐ Once
- ☐ Twice
- ☐ Three times or more

How much do you think the following impacts your employees' driving safety when at work?

	Not at all	Just a little	To some extent	Rather much	Very much
Sleepiness					
Stress					
Alcohol use					
Drug use					

Distraction or inattention

Evaluation of the PANACEA system

What is your general opinion of the PANACEA system?

☐	☐	☐	☐	☐
Very positive	Somewhat positive	Neutral	Somewhat negative	Very negative

	Completely disagree				Completely agree
I would like to have this system at my workplace.	1	2	3	4	5
If I had access to PANACEA in the future, I would be willing to use it.	1	2	3	4	5
I think the PANACEA system would improve working conditions.	1	2	3	4	5
I think a system like PANACEA could be useful for other transport modes (i.e., air, maritime, rail).	1	2	3	4	5

Several aspects are listed in the following table. Please indicate how these aspects can change if you are an operator/manager using the PANACEA system.

	Decrease	Stay the same	Increase
Safety	☐	☐	☐
Number of accidents	☐	☐	☐
Severity of accidents	☐	☐	☐
Attention towards the road	☐	☐	☐

Stress	☐	☐	☐
Fatigue	☐	☐	☐
Alcohol use	☐	☐	☐
Drug use	☐	☐	☐
Possibility to drive longer (longer trips)	☐	☐	☐
Possibility to drive longer (more years)	☐	☐	☐
Worry about system failure or data breach	☐	☐	☐
Feeling of being controlled	☐	☐	☐

Do you have any other comments about the PANACEA system?

____

____

____

____

____

Technology Acceptance Scale by van der Laan

My judgements of the PANACEA system are ... (please tick one box in every line)

Useful						Useless
Pleasant						Unpleasant
Bad						Good
Nice						Annoying
Effective						Superfluous
Irritating						Likeable
Assisting						Worthless
Undesirable						Desirable
Raising Alertness						Sleep-inducing

System Usability Scale (SUS)

	Strongly disagree				Strongly agree
I think that I would like to use this system frequently	1	2	3	4	5
I found the system unnecessarily complex	1	2	3	4	5
I thought the system was easy to use	1	2	3	4	5
I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
I found the various functions in this system were well integrated	1	2	3	4	5
I thought there was too much inconsistency in this system	1	2	3	4	5
I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
I found the system very cumbersome to use	1	2	3	4	5
I felt very confident using the system	1	2	3	4	5
I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

SHAPE Automation Trust Index (SATI)

	never						always
1)…the system was useful.	0	1	2	3	4	5	6

	never						always
2)…the system was reliable.	0	1	2	3	4	5	6

	never						always
3)…the system worked accurately.	0	1	2	3	4	5	6

	never						always
4)…the system was understandable.	0	1	2	3	4	5	6

	never						always
5)…the system worked robustly (in difficult situations, with invalid inputs, etc.).	0	1	2	3	4	5	6

	never						always
6)…I was confident when working with the system.	0	1	2	3	4	5	6

Countermeasures

Fatigue debriefing

Did you at any point receive a fatigue debriefing?

☐ Yes ☐ No

	Completely disagree				Completely agree
The recommendation levels were easy to understand.	1	2	3	4	5
The debriefing procedures were easy to follow.	1	2	3	4	5
The information/advice in the fatigue debriefing was useful.	1	2	3	4	5
The frequency of the fatigue debriefing was appropriate.	1	2	3	4	5
There has been an improvement/reduction in drivers' fatigue since the introduction of the fatigue debriefing.	1	2	3	4	5
The drivers have been open and cooperative with the fatigue debriefing.	1	2	3	4	5
The debriefing sessions were useful.	1	2	3	4	5
The safety of my drivers has been improved by the fatigue debriefing.	1	2	3	4	5
I will likely carry on using some type of fatigue debriefing in the future.	1	2	3	4	5

Fatigue alert

Did you at any point receive a fatigue alert?

☐ Yes ☐ No

	Completely disagree				Completely agree
The fatigue alert levels were easy to understand.	1	2	3	4	5
The alert notifications were easy to interpret.	1	2	3	4	5
The frequency of the fatigue alerts was appropriate.	1	2	3	4	5
These alerts have increased my awareness of how fatigued drivers are.	1	2	3	4	5
These alerts have helped me in managing fatigue within my drivers.	1	2	3	4	5
I am confident that the fatigue alerts are accurately notifying of fatigue.	1	2	3	4	5
Fatigue alerts have reduced fatigue levels in my drivers since their introduction.	1	2	3	4	5
The safety of my drivers has been improved by the fatigue report.	1	2	3	4	5

Licit Drug Debriefing

Did you at any point receive a licit drug debriefing?

☐ Yes ☐ No

	Completely disagree				Completely agree
The licit drug debriefing was easy to understand.	1	2	3	4	5
The debriefing procedures were easy to follow.	1	2	3	4	5

The information/advice in the licit drug debriefing was useful.	1	2	3	4	5
The frequency of the licit drug debriefing was appropriate.	1	2	3	4	5
The drivers have been open and cooperative with the licit drug debriefing.	1	2	3	4	5
The introduction of licit drug debriefings would reduce levels of licit drug misuse in my drivers.	1	2	3	4	5
The debriefing sessions were useful.	1	2	3	4	5
The safety of my drivers has been improved by the licit drug debriefing.	1	2	3	4	5
I will likely carry on using some type of licit drug debriefing in the future.	1	2	3	4	5

Coaching system evaluation

Thinking about the platform from which you received the countermeasure (insert the name of one of the 3 options) I found the use of the countermeasures system

Useful						Useless
Pleasant						Unpleasant
Bad						Good
Nice						Annoying
Effective						Superfluous

Irritating						Likeable
Assisting						Worthless
Undesirable						Desirable
Demotivating						Motivating

	Not at all				A lot
Since using PANACEA driver behaviour to reduce fatigue has changed.	1	2	3	4	5
Since using PANACEA driver behaviour to licit drugs has changed.	1	2	3	4	5

If PANACEA included countermeasures to other impairments how willing would you be to use it for

	Not at all willing				Very willing
Alcohol	1	2	3	4	5
Illicit drugs	1	2	3	4	5
Cognitive distraction	1	2	3	4	5

I think the PANACEA countermeasures could be useful for other transport modes (i.e., air, maritime, rail).

Completely Completely

disagree				agree
1	2	3	4	5

Appendix V Cover Sheet of Data Delivery

Data characteristic	Description
Dataset Reference ID	PANACEA_WPX_AX.X_XX: Each dataset will have a reference that will be generated by the combination of the name of the project, the Work Package and Activity in which it is generated and its version (for example: PANACEA_WP5_A5.1_01).
Dataset Name	Name of the dataset.
Dataset Description	Each dataset will have a full data description explaining the data type, provenance, origin and usefulness. Reference may be made to existing data that could be reused.
Standards and metadata	• The metadata attributes list (includes variable name, data type, format, unit, constraint, comment). If too many variables, add a link to the file that describe the attribute list. • The used methodologies
File format	All the format that defines data (e.g., .xlsx, .csv).
Data Origin	Specify the origin of the data (e.g., simulator study done by … in …)
Data Size	State the expected size of the data (xx KB/MB/GB/TB). If not precise, write smaller/greater than before xx.
Data Sharing	Explanation of the sharing policies related to the dataset between the next options: • **Open**: Open for public use. • **Embargo**: It will become public when the embargo period applied by the publisher is over. In case it is categorised as embargo the end date of the embargo period must be written in DD/MM/YYYY format. • **Restricted**: Only for project internal use. Each dataset must have its distribution license. Provide information about personal data and mention if the data is anonymised or not. Inform if the dataset entails personal data and how this issue is considered.
Archiving and Preservation	The preservation guarantee and the data storage during and after the project (for example: databases, institutional repositories, public repositories, etc.)

Data characteristic	Description
Re-used existing data	Y/N. If Yes, state the re-used data and how/from where they were retrieved. If N, state if newly collected/created.
Data Utility	Outline to whom the dataset could be useful – potential secondary users.
Link to Dataset	URL link to actual dataset with the same filename (if **Open**)

Appendix VI Internal Study Report Template

Table of content for internal deliverable:

1 Study name [UCA-S, UCA-R, UCB-S1, UCB-S2, UCB-R, UCC-R, or Roadside]

1.1 Research questions

1.2 Participants

1.3 Simulator/Vehicles

1.4 Simulator scenario/Environment

1.5 Driver impairments

1.6 Countermeasures

1.7 Study design

1.8 Data gathering tools

1.9 Data analysis

1.10 Results

1.11 Conclusions