Assuring the safety of connected and automated vehicle trials on the public highway

Guidance for trialling organisations

endeavour

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Foreword

This document is one out of a suite of three stakeholder specific guidance documents on the safety assurance of trials. This document is aimed at trialling organisations (TOs) involved in testing and trialling connected and automated vehicles (CAVs) within the UK. The other two documents are aimed at local authorities and insurers. These documents have been developed by TRL as a key output from our work on CAV safety assurance within Project Endeavour.

1. Introduction

1.1 . What is safety assurance and what does it mean for Trialling Organisations (TOs)?

1.1.1 What is safety assurance and why is it important?

As CAVs are evolving, there is an increasing demand to test and trial them on the UK road network. Demonstrating the safety of CAV trials is vital to ensure that there is strong public confidence in CAVs and related mobility services. As such, ensuring best practice approaches to safety assurance during public trials is key to the successful introduction of CAVs onto UK roads.

Safety assurance can be defined as a method of demonstrating that a CAV under test has the required processes and controls in place to ensure that the risks have been assessed and mitigated to as low as reasonably practicable (ALARP). The safety assurance process can also be a useful opportunity for stakeholders to share information and learn from one another, which ultimately helps drive innovation.

1.1.2 What does safety assurance mean for TOs?

TOs are responsible for a trial's safety and, in accordance with the Department for Transport's (DfT's) Code of Practice (CoP) for automated vehicle trialling, they need to demonstrate to external stakeholders (e.g. local authorities, landowners and insurers) that a suitable safety case is in place and that the safety case follows best practice. A safety case is a structured argument supported by a body of evidence that demonstrates all the safety risks have been identified and appropriate controls have been put in place to minimise the risk of harm. The safety case also demonstrates compliance with all relevant standards, guidance and legislation.

1.2 What progress has been made to date in safety assurance for CAV trials?

1.2.1 Safety assurance requirements, standards and guidance documents

Figure 1 provides a snapshot of some of the key requirements, standards and guidance documents that have been produced related to general trial safety and the specific requirements of a safety case.


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Figure 1: CAV safety regulations, standards and guidance landscape

The requirements, standards and guidance documents of most relevance to safety assurance include:

- The DfT Code of Practice for automated vehicle trialling – this code of practice provides guidance on trialling automated vehicle technologies on public roads or in public places in the UK. It makes recommendations on how to maintain safety and minimise potential risks. There is also guidance on how to improve the transparency of trials and how to engage with the public, authorities and other relevant bodies when planning trials.
- BSI PAS 1881 Assuring the Safety of Automated Vehicle Trials and Testing – this standard is intended to support the safe testing and trialling of CAVs. It specifies best practice for safety cases for automated vehicle trials and development testing in the UK to demonstrate that activities can be undertaken safely.

The team at TRL has played a key role in developing current guidance and standards for CAV trials. We co-authored BS PAS 1881 – Assuring safety for automated vehicle trials and testing and the Zenzic Safety Case Framework for CAV testing and trialling across all the UK testbeds.

1.2.2 Safety assurance within CAV testing and trials

Alongside the development of safety assurance documentation, there has been extensive testing and trialling activity underway within the UK. At TRL, we've been gaining experience in safety assurance due to our involvement in a wide range of these trials including GATEWAY, Streetwise, DRIVEN and the HelmUK HGV platooning trials. TRL also led the build of the Smart Mobility Living Lab (SMLL) in London – the UK's most advanced real-world connected environment for testing future mobility technologies. For the SMLL we have put all the necessary processes in place to ensure that any trials are conducted safely and in line with current best practice, guidance and standards.

Exposure to diverse projects of different scales and nature has allowed us at TRL to develop deep technical understanding of a range of elements related to safety assurance including: creating and reviewing safety cases, undertaking risk assessments, developing risk mitigation strategies, supporting trials, conducting emergency response tests, and establishing testbed procedures.

1.3 Project Endeavour – improving safety assurance for future CAV trials

Project Endeavour is a collaborative, consortium led project, part-funded by the Centre for Connected and Autonomous Vehicles (CCAV) and delivered in partnership with Innovate UK. It is a mobility project designed to fast-track the introduction of connected and automated vehicle (CAV) services across the UK and maximise the potential of this new technology to shape the future of mobility. TRL is a key partner in Project Endeavour and we are bringing our safety and compliance expertise to deliver a dedicated safety assurance workstream. The focus of this workstream is to improve the level of understanding of safety assurance among all stakeholders. Also, to promote the adoption of a streamlined and consistent approach to safety assurance amongst stakeholders to help reduce barriers to trialling and innovation across the UK.

To help define the activity within the safety assurance workstream on Project Endeavour, TRL conducted a series of interviews with stakeholders involved in CAV trials including: trialling organisations, highway and local authorities, testbeds and landowners, insurers and insurance bodies. Their input is gratefully acknowledged. The aim of this engagement was to find out more about their current involvement and capabilities in conducting and supporting CAV trials, their future aspirations, and the areas in which we may assist them in fulfilling those aspirations. This stakeholder engagement identified that there were some key gaps in knowledge and inconsistencies in the approach taken towards safety assurance of CAV trials. To address this, one output of the project is to develop bespoke stakeholder specific guidance documents for trialling organisations, local authorities and insurers.

1.4 What is this guidance document and what does it include?

This guidance document is aimed at TOs involved in CAV trialling within the UK.

Within our engagement with TOs, there were a number of areas of CAV trialling in which TOs commonly reported difficulty, often due to ambiguity of requirements or a lack of previous experience in the area. This document is therefore not intended to provide a broad overview of safety assurance – as there are already existing documents serving this purpose (as outlined in **Figure 1**). Instead it attempts to address some of the identified gaps in knowledge through exploring in depth a handful of key topics. For each topic, guidance is provided on what is expected from TOs, useful considerations when implementing these processes, and where relevant, case studies highlighting examples of good practice.

The topics explored include:

- Stakeholder engagement – who should you engage with and how?
- Emergency response planning – what does emergency planning involve and how should you prepare for emergencies?
- Ethics – what is research ethics and when is ethical approval for trials required?

This document concludes by outlining some further services which TRL is able to offer to help further assist TOs in the safety assurance of their testing and trialling activities.

2. Stakeholder engagement

This section provides some guidance on stakeholder engagement which will help TOs to conform with the requirements outlined in BS PAS 1881 and the DfT's CoP for automated vehicle trialling. The guidance includes an outline of who to engage with and a suggested process to follow.

2.1 Who should you engage with?

Table 1 outlines the range of stakeholders whom TOs should engage with prior to commencing any public trials.

Table 1: Key stakeholders to engage with

Stakeholder	Key requirements
Centre for Connected and Autonomous Vehicles (CCA	▪ Need to be informed about the intention of the TO to conduct a trial on UK public roads.
Local authorities, landowners, road authorities	▪ Permission to conduct the trial will need to be sought from landowners. ▪ As a minimum, all of these stakeholders are likely to request elements such as the route assessment and the emergency response plan from the safety case. They may expect to see evidence that the safety case is compliant with the relevant standards, including but not limited to the DfT's CoP for automated vehicle trialling and BS PAS 1881. ▪ TOs should consider whether their trial requires additional licencing, for example for carrying passengers. ▪ TOs should consult the relevant authority regarding any modifications required to the trial area, such as trial-related street furniture or closure of roads.
Emergency services	▪ Police and fire and rescue services need to be aware of the TOs emergency response plan and their role in the event of an incident. This might include technical information such as the location of safety equipment (for example, isolation switches, safe cutting points) or any modifications made to the base vehicle.
General public	▪ The CoP requires TOs to produce an abridged version of their safety case and this should be made publicly available. Note: guidance on what should be included in an abridged safety case can be found in the Zenzic's Safety Case Framework: The Guidance Edition for Creators. ▪ TRL have produced public safety cases for the StreetWise project and the Smart Mobility Living Lab (SMLL) Shared Research Programme (SRP) ▪ TOs may wish to partake in other forms of public engagement through their wider marketing strategy for the trial.
Insurers	▪ The CoP requires any trial vehicle to be appropriately insured before going on public roads. As minimum, insurers are likely to review the proposed Operational Design Domain (ODD), safety driver training, and details of the system safety from the safety case before underwriting a trial.

2.2 The stakeholder engagement process

Figure 2 outlines a process which TOs may wish to follow to ensure robust stakeholder engagement.

TOs should consider the following information when conducting each stage of their engagement:

- Stakeholders should be given adequate opportunity to discuss the trial and any concerns they may have.
- Some stakeholders will be inexperienced in CAVs and might not have seen a CAV operate. As part of the safety assurance process, TOs should use the pre-trial engagement phase to educate these stakeholders and familiarise them with the technology.
- It is important that stakeholders are prepared for the consultations with the TO so that they can play an active role in the review process. TOs should emphasise this importance and assist stakeholders to prepare where possible.
- It is advisable to put technical information into context for those unfamiliar with CAVs. This might include inviting stakeholders to the trial site or a private testing site to see the vehicles in use.

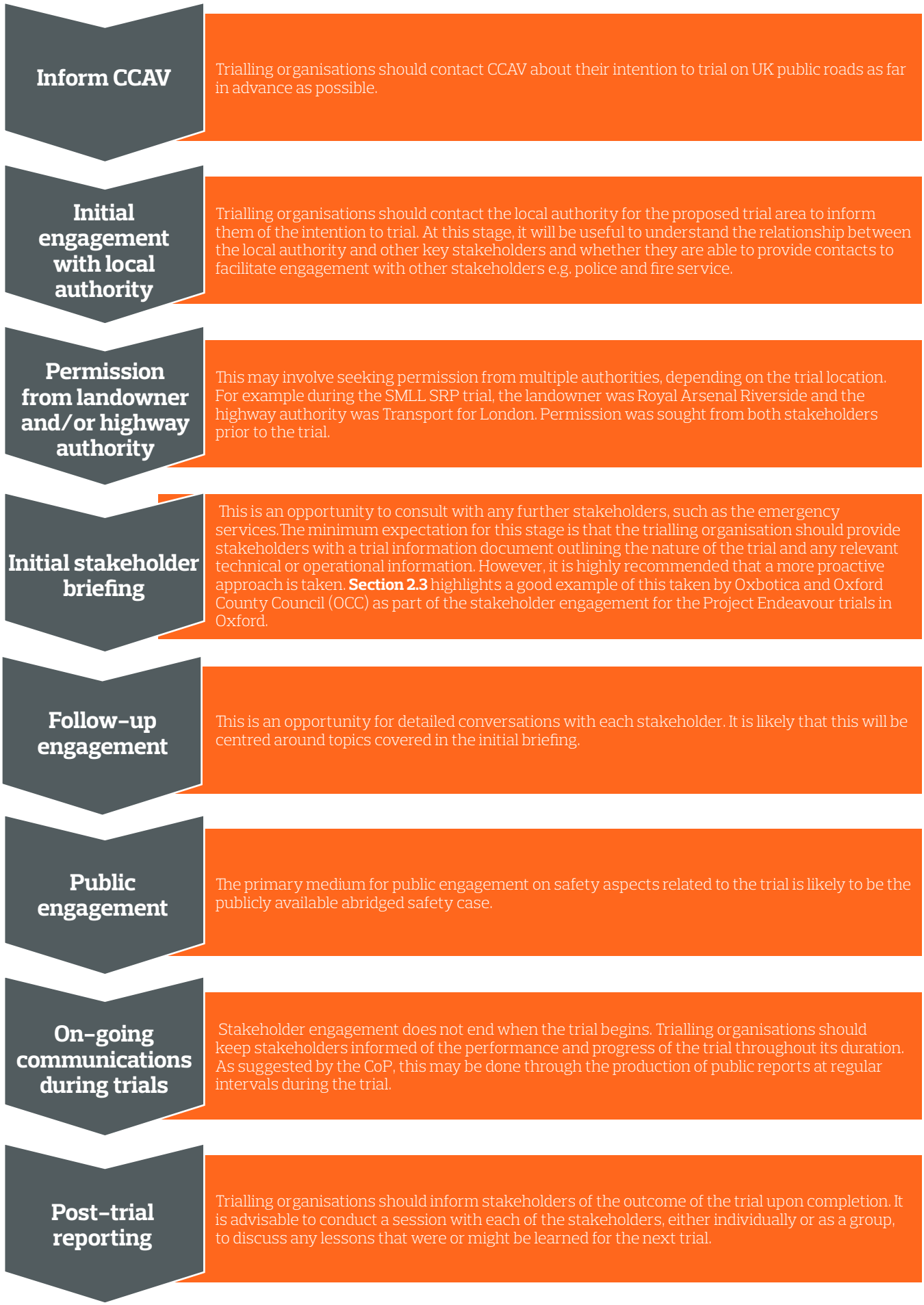


Figure 2: Proposed stakeholder engagement process for TOs

2.3 Case study: Oxbotica's stakeholder briefing for Project Endeavour

2.3.1 Overview

Oxbotica is a UK autonomous vehicle software company and is the lead trialling organisation for Project Endeavour. In October 2020, Oxbotica and Oxfordshire County Council (OCC) arranged an online stakeholder briefing in advance of the Endeavour public trials in Oxford. This was a two-hour session in which Oxbotica provided an overview of Endeavour and presented some key elements of their vehicle system and their safety case. At this stage, permissions for the trial had been granted by the relevant authorities. Oxbotica worked very closely with OCC during the planning of this trial, with OCC acting as a liaison between Oxbotica and other stakeholders.

2.3.2 Contents of the briefing

- An introduction to the Endeavour project and to the safety assurance process.
- An outline of the importance of each stakeholder with regards to the trial, and why it is necessary that they are familiar with the vehicle and understand their responsibilities.
- A video tour of the vehicle. This outlined the AV hardware (location of sensors, cameras, and computers), safety measures such as e-stop buttons and electrical isolation switches, and information about vehicle cutting points for emergency services.
- A video demonstration of the ADS completing an automated trip around Oxford. This included a demonstration of the interaction between the safety driver, the automated control system engineer (ACSO), and the vehicle.
- Details of the proposed trial route.
- An overview of safety case structure and content. This included both generic and trial-specific details. Elements of note included the scope and introduction, the trial Operational Design Domain (ODD), safety driver training, and system safety.
- Oxbotica outlined the standards which are relevant to automated vehicle trialling and which they have incorporated into their processes.
- An overview of the emergency response plan and the documents contained within. This outlined the key processes within those plans, and how risks are being managed, mitigated, and recorded.
- A Q&A session, where stakeholders could discuss any concerns and provide feedback.

2.3.3 Key benefits of this approach

- The briefing was recorded, so the information was available to stakeholders to refer to or disseminate to their team, rather than relying on a single point of contact between each stakeholder and the TO. The recording also acts as useful evidence and can be included in the safety case.
- The interactive nature of the briefing enabled stakeholders to ask questions and give suggestions. This resulted in a better learning experience for all parties than simply providing stakeholders with a trial information document.
- The vehicle tour and demonstration provided useful context for the stakeholders. It made the trial operation and content of the safety case more tangible for those who were not previously familiar with the technology.
- The overview of the safety case structure and emergency response plan documentation assisted the stakeholders in understanding the holistic approach to safety assurance taken by Oxbotica.
- The briefing now forms a template that Oxbotica can easily adapt for other trial locations.

3. Emergency response planning

This section provides a detailed overview of the key elements of emergency response planning which will help TOs to conform with the requirements outlined in BS PAS 1881 and the DfT's CoP for automated vehicle trialling.

3.1 What is emergency response planning and why is it important?

The purpose of emergency response planning is to:

- Identify what incidents might occur during trialling;
- Ensure that any incidents that do occur are dealt with promptly, safely and effectively both in terms of response and escalation;
- Ensure that all trial teams and stakeholders are aware of their roles and responsibilities when responding to incidents; and
- Facilitate effective and consistent communication during and following an incident.

Robust emergency response planning is important to help minimise injuries, reduce the potential for disruption in and around the trial area, and to tackle the reputational threat of an incident occurring during the trial.

3.2 Key stakeholders to involve in the emergency response planning process

Table 2 outlines the key stakeholders that should be involved in the emergency response planning process. Emergency response documents should be shared with stakeholders as early as possible to seek their feedback and ensure that the plan is practicable and covers all required elements.

Table 2: Stakeholders to involve in the emergency response planning process

Stakeholder	Key requirements
Trials team	▪ Need to be trained on all emergency response and incident reporting procedures
Wider project stakeholders	▪ Need to have an awareness of the overall emergency response planning process ▪ Need to provide relevant escalation contacts for the emergency response plan and crisis communication plan ▪ Need a more focused briefing on the elements relevant to them, for example their role in escalation and crisis communications
Testbed	▪ If trialling within a testbed, the testbed will have their own emergency response processes so the TO will need to understand them and align their emergency response plan with them ▪ Need to provide relevant escalation contacts for the emergency response plan and crisis communication plan ▪ Need to have an awareness of the emergency response plan and crisis communication plan and their role within them
Landlord/highway authority/local authority	▪ Need to provide relevant escalation contacts for the emergency response plan and crisis communication plan ▪ Need to have an awareness of the emergency response plan and crisis communication plan and their role within them
Police	▪ Need to provide relevant escalation contacts for the emergency response plan ▪ Need to have an awareness of the emergency response plan ▪ Suggestion for them to log information on their systems and provide a reference number for TOs to use and be included within the emergency response plan and quoted when escalating an incident
Fire and Rescue Service	▪ Need to provide relevant escalation contacts for the emergency response plan ▪ Need to have an awareness of the emergency response plan ▪ Need to be provided with technical information about the non-standard features of the vehicle and systems for effective response

3.3 Procedures and process flow for emergency response planning

Figure 3 outlines the suggested process flow for emergency response planning.

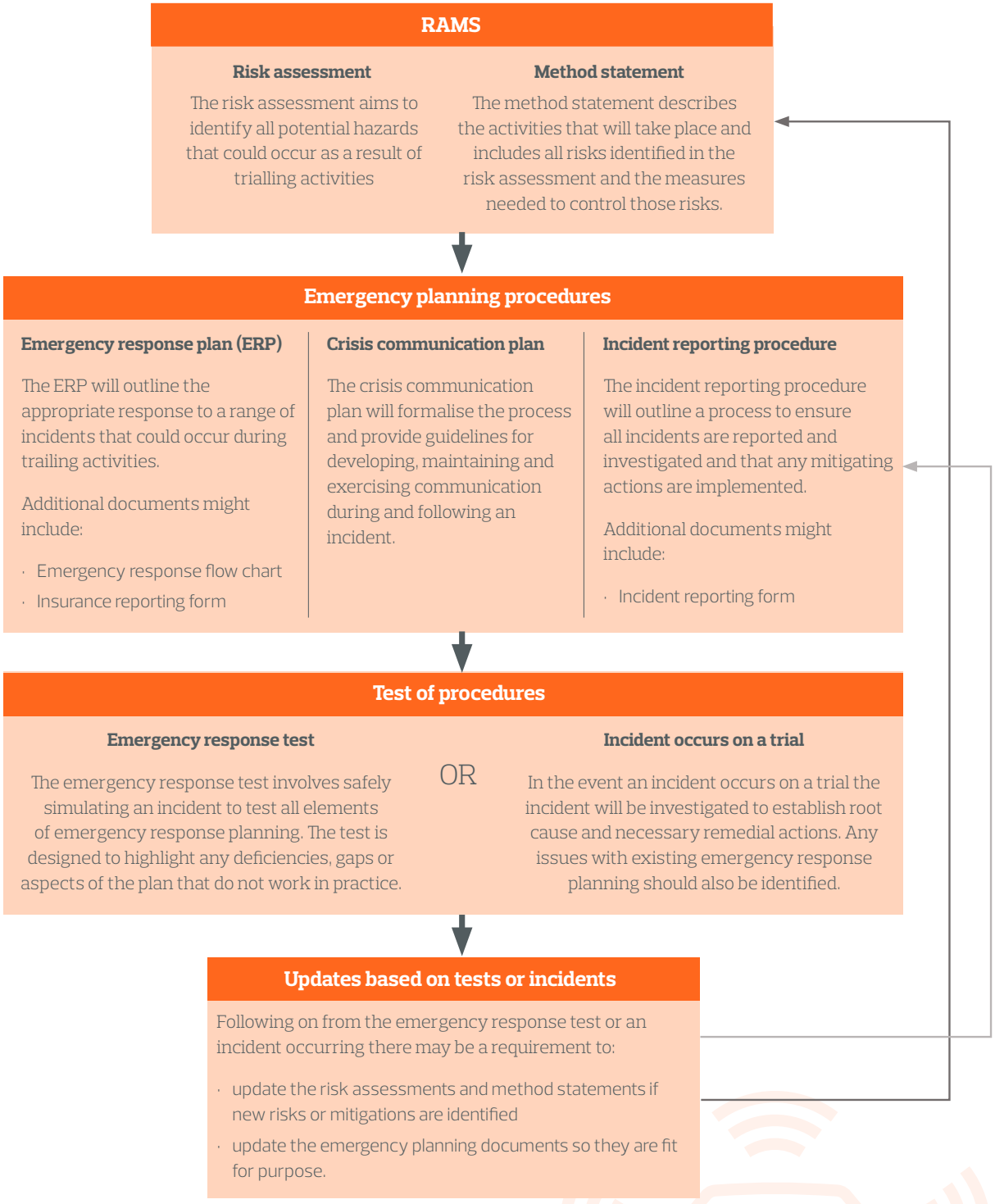


Figure 3: Process flow for emergency response planning.

3.4 Outline of key procedures in emergency response planning

This section provides information regarding the content that should be included within emergency response planning documentation including:

- Emergency response plan
- Crisis communication plan
- Incident reporting procedure

3.4.1 Emergency response plan

Table 3 outlines the key elements that could be included within an emergency response plan.

Table 3: Key content to be considered in an emergency response plan

Section	Content
Introduction	▪ Summary of the purpose and objectives of the emergency response plan
Trial overview	▪ An overview of the key information related to the trial, e.g. information about the trial location, an overview of the vehicles and trial and route information
Roles and responsibilities	▪ An outline of high-level roles and detailed responsibilities of all individuals involved in the emergency response plan ▪ Roles typically include safety driver, test assistant/engineer, incident manager, marshal, steward, first aider
Emergency response equipment & documentation	▪ An outline of all equipment and documentation that should be available (either in the vehicles or on-site) to assist with the emergency response and the process in place to check that these are all available and up to date
Emergency response plan	▪ Incident categories – categorisation of incidents, for example by levels of severity, with some related incident examples for each category ▪ Appropriate emergency response – step-by-step outline of the appropriate response to take for a range of incidents (as identified in the risk assessments for the trial)
Communication, escalation and reporting process	▪ Communication with stakeholders to report the incident, including the emergency services, recovery services, road authorities, insurers. This should include all relevant contact details and communication timescales ▪ Escalation to project stakeholders to report the incident. This should include all relevant contact details and escalation timescales ▪ Incident communication guidelines, for example what specific information to relay about the incident ▪ Reference to the crisis communication plan including instructions that no other person other than the designated spokesperson should make any statements to the media ▪ Reference to the incident reporting procedure
Evacuation plan	▪ Evacuation procedure defining specific roles and responsibilities ▪ Evacuation points
Welfare plan	A welfare plan is required to oversee the wellbeing of those who are involved within an incident. ▪ Welfare procedure defining specific roles and responsibilities ▪ Identified places of shelter in the event of poor weather conditions ▪ Welfare packs (including things like bottles of water, ponchos and space blankets)
Vehicle recovery information	▪ Details of vehicle recovery provider including name and contact details ▪ Membership details for roadside assistance ▪ Key information that should be provided when contacting the vehicle recovery provider
Information for the emergency/vehicle recovery services	▪ Information on vehicle specific hazards that could impact safety e.g. lidar safety requirements, battery isolation points, safe extraction points and the location of cables ▪ Information on how to ensure vehicle motion is disabled ▪ Information on the vehicle load, for example presence of any hazardous features

Table 3: Key content to be considered in an emergency response plan – continued

Section	Content
Additional documents that might be useful to develop for an emergency response plan	
Emergency response quick reference guide	The would be a short quick reference document to help readers navigate the emergency response in an incident. Contents can include: ▪ Emergency response flow chart ▪ Emergency contacts ▪ Step-by-step emergency response actions – per incident type
Insurance reporting form	This form is to be followed and completed to record the details of an incident for insurance purposes. Contents can include: ▪ Insurance number to call ▪ Section to record driver and vehicle details ▪ Section to record incident details ▪ Section to record third party details ▪ Tear-off forms to give to third parties for exchange of insurance details

3.4.2 Crisis communications plan

Table 4 outlines the key elements that could be included within a crisis communications plan.

Table 4: Key content to be considered in a crisis communications plan

Section	Content
Introduction	▪ Summary of the purpose and objectives of the crisis communications plan.
Relationship to the emergency response plan	▪ How the crisis communication plan fits with the emergency response plan ▪ Outline of key incident categories
Roles and responsibilities	▪ An outline of high-level roles and detailed responsibilities of all individuals involved in the crisis communications plan ▪ Roles typically include incident manager, project lead, crisis communication steering group chair, crisis communication steering group members, communication representatives
Crisis communications procedure	▪ Instigating the crisis communications procedure, for example when to instigate the crisis communications procedure and what steps to follow ▪ Composition of the crisis communications steering group, including timescales, purpose, representatives, procedure to follow to determine appropriate response and co-ordinate the communications plan, and the nomination of spokespersons
Key contacts	▪ Steering group members - including representatives from trialling organisation/wider consortium ▪ Communication representatives – including communication representatives from trialling organisation/wider consortium and communication representatives from external organisations e.g. road authorities, local authorities, emergency services etc
Draft statements	▪ Draft statements for a number of different scenarios should be created ▪ Scenarios could include fatalities, serious injuries, minor injuries, damage only collisions, secondary incident (i.e. vicinity collision), fire, security threat, physical or cyber-attack and near misses
Additional elements that might be useful to develop for a crisis communications plan	
Process flow diagram	▪ A flow diagram providing an overview of the crisis communications process
Quick reference checklist	▪ A checklist of prompts which can be referred to in a crisis to ensure that all elements of the crisis communications plan are actioned

3.4.3 Incident reporting procedure

Table 5 outlines the key elements that could be included within the incident reporting procedure.

Table 5: Key content to be considered in the incident reporting procedure

Section	Content
Introduction	▪ Summary of the purpose and objectives of the incident reporting procedure
Roles and responsibilities	▪ An outline of high-level roles and detailed responsibilities of all individuals involved in the incident reporting procedure. ▪ Roles typically include incident manager, safety driver, risk and safety manager
Definitions	▪ Incident categories
Incident reporting procedure	▪ Completing the incident reporting form ▪ Completing the insurance bump card ▪ Reporting of non-emergency incidents to the Police ▪ Suspending trials ▪ Incident investigation ▪ Updates to the risk assessment, method statement and emergency response plan
Incident reporting form	▪ Overview of the incident, for example who was involved, time, date, location, weather conditions, road conditions, severity of incident, any damage or injuries ▪ Description of the incident, for example what happened before and during incident, likely route cause, and what action was taken

Notes:

- You might wish to consider combining the incident response procedure with a near miss procedure to capture events that occur on trials that did not result in injury and damage but had the potential to do.
- The incident reporting procedure is a key element of the information management plan (IMP) for a trial. The IMP identifies relevant data to be collected and managed to help facilitate incident investigations. Further information on the requirements for the information management plan can be found in BSI PAS 1882 – Data collection and management for automated vehicle trials for the purpose of incident investigation.

3.5 How to test your emergency response planning

In order to ensure robust testing of your emergency response planning, it is important to thoroughly plan the approach to both conducting the test and capturing the results. This can be achieved through the creation of a test plan. An example template for a test plan is included **Table 6**.

Table 6: Example template for an emergency response

Test plan	
Describe the test Scenario	
Proposed test participants	
Test manager	
Proposed test date and time	
Test plan	▪ How will the test be carried out? ▪ Who will need to be aware of the test? ▪ What instructions will they be provided?
Test result, findings and improvements	
Test time and date	
Test participants	
Test findings	
Follow-up actions and improvements	

- The test plan should seek to test all procedures within your emergency response planning including the emergency response procedures, crisis communications procedure and the incident reporting procedure.
- All those involved in the test should be notified in advance including any relevant escalation contacts.
- Test instructions will need to be provided for individual stakeholders so they are clear on what they should or should not be doing. For example, it is prudent not to involve the emergency services during a test. A suggested approach would be to provide a test instruction sheet to individuals involved in the test which could be customised for different roles in the test, for example safety driver, or marshal. The instruction sheets would either specify to "record" actions you would take or, where appropriate, to take actions such as escalating or completing forms.
- Populated test sheets could then be reviewed to determine any issues experienced during the test. In addition, a post-test review meeting could also be held with all key stakeholders to generate wider feedback on the results and learning from the test.
- The results of the test should then generate a series of follow-up actions or improvements to be made to your emergency response planning to ensure that the processes in place are robust.

3.6 Case study: SMLL Shared research programme CAV trials – Emergency response testing

3.6.1 Overview

The creation of the Smart Mobility Living Lab (SMLL) was a co-innovation project lead by TRL and a consortium of partners to deliver a state-of-the-art testbed for Connected and Automated Mobility (CAM). In 2019, the SMLL Shared Research Programme undertook a series of CAV trials in partnership with trialling organisation StreetDrone in order to accelerate learning and deliver research and development objectives. A key element of the trial was the establishment of a safety case and related procedures. Included within this were procedures for emergency response planning and the subsequent testing of these procedures.

3.6.2 Key learnings

This section outlines some of the key learnings from the emergency response tests undertaken in the trial:

- It is important to outline some incident communication guidelines to be referred to when communicating/ escalating an incident. This will ensure that all details of the incident are captured and accurately communicated. Also, that certain details are not communicated to avoid a breach of GDPR, for example details of people involved in incidents. Any verbal communication of incidents should be followed at the earliest opportunity with a written summary of the incident to avoid any miscommunication of incident details.
- Test managers should be independent of the test rather than participating in the test so that they are better able to oversee the actions taken by all stakeholders involved in the test.
- It is worth checking before finalising emergency response documentation that all the contact names and numbers are correct – this often comes up as an issue during tests.
- Ensure that there are nominated deputies for all key roles and that their contacts are also included in the procedures.
- Procedures related to emergency response planning are complex so spend time to adequately train/brief all stakeholders involved in the emergency response process; do not just rely on them reading the documentation. Consider testing stakeholders during training to ensure everyone has a good level of understanding and awareness.
- If the results of the test are mixed, or there is a requirement for lots of updates, perhaps schedule a follow-up test to ensure issues have been resolved.

4. Research ethics

4.1 What is research ethics and why is it needed?

Within BS PAS 1881 (Section 5.14) reference is made to the requirement for trialling organisations to conduct an ethics impact assessment prior to trials or testing in the public domain. Here it stipulates that:

- Public trials shall obtain approval from an ethics committee prior to any testing that could impact on a member of the public or participant, whether these people are directly or indirectly affected.
- The ethics approval process shall be proportionate to the potential impact.
- Process outcomes shall be included within the safety case and shall detail how approval was attained.

BS PAS 1881 also defines that an ethics committee is a group of qualified individuals formed to protect the interests of participants or persons affected by the trial and to ensure moral issues are addressed.

Research ethics refers to the moral values guiding research, from its initiation through to close and publication. Any CAV trial should be delivering the highest ethical standards, as well as innovating the transport sector. An ethics review of a CAV trial is intended to ensure that the dignity, rights and welfare of research participants are protected. Conducting research to high ethical standards helps to ensure that it delivers benefits and minimises the risk of harm. The benefits of the trial should always outweigh the ethical impacts.

The nature of the ethics impact assessment is not defined in the standard. We would interpret this as a review that will help a trialling organisation to understand and document the potential ethical impacts of their trial. This will help them determine whether an ethics review is required, and if so, the nature of that review e.g. a full Research Ethics Committee, or a smaller Ethics Panel review as appropriate to the ethical challenges raised by the trial.

4.2 Types of research that require ethical approval

Each CAV trial is testing different technology, scenarios, and has different levels of involvement with people. Each trial is complex and unique in its potential benefits, and therefore its risk during delivery. This means that each trial must be separately assessed in terms of ethics. However, it does not mean that we must always go to extreme lengths in considering ethics, and the effort involved in an ethics review must be proportionate to the risk.

The ethics impact assessment is outlined in **Figure 4**, and any decision not to proceed with ethics review should be formally documented.

Human data – At least one is true:

- No research data from human participants
- Research data is pre-existing and anonymous
- Research data is limited to topics within professional competence of the individuals

New human research data – All are true, when new research data is collected from humans:

- No personal data is being collected other than name, publicly available contact details and a record of consent
- The data is not likely to upset those involved in the research
- No vulnerable or dependent groups

Any research – At least one is true:

- No increased risk of harm to participants, researchers, or bystanders
- The risk of harm is controlled by risk assessment and a safety case

Figure 4: Outline of an ethics impact assessment

If the ethics impact assessment indicates that an ethics review is required, then the most important factor is whether the trial might involve any increased risk of harm to the participants, for example if the trial vehicle were to crash. We might imagine a trial to test the functional safety of a CAV, where the roads are closed off to the public and only a safety driver, employed by the trialling organisation, is involved. The moral question is whether the company is right to put that driver in the trial, and have enough risk mitigation strategies been put in place to satisfy the company and the driver that the risk is sufficiently lowered? In this case a risk assessment and appropriate employee liability insurance are required, but a full Research Ethics Committee with an external panel might seem disproportionate, especially if the trialling organisation has prior experience of such trials. If it were the first trial ever run by a trialling organisation, then a full Research Ethics Committee would be appropriate.

Conversely, if we imagine a trial examining user uptake of an automated bus service on a popular route in a city, with local passengers using the service and their views being captured in a post-use survey, then the effort must be proportionately higher because the risks are much higher. In this case it would be much more relevant to form a full Research Ethics Committee and involve at least one independent member, in order to fully assess the risks and consequent moral considerations.

In most cases where a non-complex trial is following recognised ethical principles a relatively 'light touch' ethics review can be used (Ethics Panel). An example might be where a survey is used to assess market uptake of a future automated ride share service. However, if the trial involved passengers riding in the CAV ride share service and then providing feedback about their experiences, then a full Research Ethics Committee may be more appropriate. This would involve at least one external participant on the panel to assess the trial and documentation. All trialling organisations should use their own judgement to decide what levels of ethics assessments should be applied. If in doubt, then take a more cautious approach and use the more demanding level of ethics review or seek advice from an appropriately experience organisation such as TRL.

It is also worth noting that there are a number of other conditions that may mean a full Research Ethics Committee review is more relevant. These include:

1. When the research involves persons who may be unable to give their real consent E.g. vulnerable older people, children under the age of 16, those with a learning disability or cognitive impairment, individuals in a dependent or unequal relationship including employees, participating organisations, hospital patients and prison inmates. Pregnant and elderly people might also need special consideration for CAV trials in terms of mobility and access of the vehicle.
2. When there is deception or withholding of information that would substantively affect people's ability to give informed consent.
3. When the research is conducted without participants' full and informed consent at the time the study is carried out.
4. When the research involves sensitive topics (e.g. illegal behaviour or health).
5. When the research involves access to records containing personal or confidential information that could identify individuals.
6. When a Disclosure and Barring Service (DBS) check (previously CRB check) is required.
7. When the project needs to be submitted for external research ethics approval (e.g. NHS research approval when working with patient groups).
8. When the research project involves releasing personal information about participants to a third party.
9. When the project involves groups where permission of a gatekeeper is normally required for initial access to members – e.g. ethnic or cultural groups, native peoples or indigenous communities, patients.

In terms of the detail that should be submitted to an ethics review, then this may include the documents set out in **Table 7**.

Table 7: Indicative list of documents to be included for ethics review

Document	Description
As a minimum requirement	
Trial overview	This should describe: ▪ The trial and its aims ▪ Which organisation is responsible for obtaining ethical approval ▪ Which organisation will be directly undertaking the trial ▪ Where the trial will be carried out
Research study plan	This should describe: ▪ Source of the participants in the trial ▪ What are the time or other burdens on participants? Have these been minimised (consistent with the aims of the research)? Will the burden be explained to potential participants before they agree to help? ▪ What are the potential adverse effects, risks or hazards for: – Research participants? – Researchers? – Members of the public or others? ▪ What provisions are there for monitoring to detect adverse effects and for halting the trial if there is cause for concern? ▪ What are the potential benefits for research participants? ▪ What are the potential benefits of the trial for the trialling organisation and for society? ▪ What type of data collection methods will be used for this trial? ▪ What are the arrangements for the collection, retention, use and disposal of trial data? ▪ Has a Privacy Impact Assessment (PIA) been completed? ▪ What arrangements have been made for debriefing, support and feedback to participants? ▪ Are employees being used as participants in the current study? ▪ Does the trial need to be submitted to an NHS Research Ethics Committee or any other external ethics committee for research ethics approval?
Example of participant consent form	In order to use personal data for research you need two bases: the ethical basis (informed consent) and the legal basis (GDPR). The consent form must include: ▪ Simple clear questions to provide informed ethical consent ▪ Simple clear questions to cover consent to the use of data
Example of information sheet	The information sheet should include: ▪ The title, invitation, and purpose of the trial ▪ Why the participant was chosen, what they will have to do, and what information will be gathered and how it will be used ▪ The potential benefits and possible disadvantages and risks of participation ▪ How the trial results will be used ▪ Ethical review and who completed it ▪ Contacts for further information
Privacy notice	Where research involves using personal data, under Data Protection Legislation participants must be informed of the following: ▪ The identity and contact details of the data controller and the data protection officer ▪ The purpose of the processing and the lawful basis for the processing ▪ The categories of personal data that will be collected ▪ The recipients of the personal data ▪ Details of any transfers to countries outside the European Economic Area (EEA) and safeguards ▪ The retention period for the data ▪ The participant's data rights ▪ The contact details for lodging a complaint
Other additional evidence (optional)	
This may include:	▪ Risk assessments ▪ Method statements ▪ Data handling plans ▪ Route assessments

4.3 Case study: SMLL Shared research programme CAV trials – Ethics approval process

4.3.1 Overview

This case study details the ethics approval process for the SMLL Shared Research programme CAV trials undertaken in partnership with trialling organisation StreetDrone. These trials aimed to understand the challenges and opportunities facing the development of CAVs and the services they could enable. The trials were conducted over 2 phases. The first phase (November 2019) involved operation of the vehicles within a public area. The second phase (December 2019) involved research on participants riding the AV around the route and then being asked to complete a questionnaire.

4.3.2 Ethics approval process

In line with industry best practice and TRL ethical working practices, participant research (included within Phase 2 of the trial) requires an ethics review to be undertaken. For this trial, the ethic approval decision was taken to a full Research Ethics Committee which included an independent member to ensure proper consideration was given to the risk of harm versus the benefit to society resulting from the study.

To provide the required evidence for the ethics approval process several documents were submitted including:

- The research study plan including the user insight survey questions
- Information sheet and privacy notice for participants
- The consent form for participants including questions to ensure that participants understood the information and risks and consent to both the AV ride and the user insight survey.

Furthermore, some of the key trial documentation was updated for Phase 2 of the trial to account for the involvement of participants in a safe and ethical manner (e.g. risk assessments, method statements, data handling plans, safety driver documentation, abort criteria, emergency response plan etc).

On reviewing this evidence and meeting with the Research Ethics Committee there were a series of additional actions identified to ensure the safety and comfort of staff and participants.

Key recommendations	Actions taken
Vehicle modifications (internal and external) need to be reviewed for crash safety. The trialling vehicle had been modified to enable automated control of certain driving functions and to facilitate testing. The modifications had been conducted in line with the standards but there was no formal documentation to support this. TRL conducted a review of these modifications and suggested some mitigations that could be implemented to reduce the risk of these modifications	Series of operational mitigations put in place for trial Phase 2.
Detailed evidence of fault injection training is required. A key element of the safety of trials is the role of the Safety Driver. The ethics process scrutinised the training and experience of the Safety Drivers and emphasised the importance of fault injection testing to prepare Safety Drivers for operating AV. In this example, Fault injection testing is a software testing method which deliberately introduces errors to the system to test the effectiveness of the response of the safety driver in overriding the systems.	StreetDrone provided more information about fault injection testing.
Active recruitment of participants rather than targeting 'walk ons'. Through the ethics process a number of methods of participant recruitment were explored. The chosen method of recruitment was to get selected groups to sign up using an event management tool. The benefits of this method were: ▪ Allow active targeting of specific participant groups ▪ Provide visibility and tracking of the recruitment process ▪ Eliminate the need for lone working in remote locations to recruit participants	Participants recruited actively from key organisations and local residents to help ensure uptake and to provide accountability

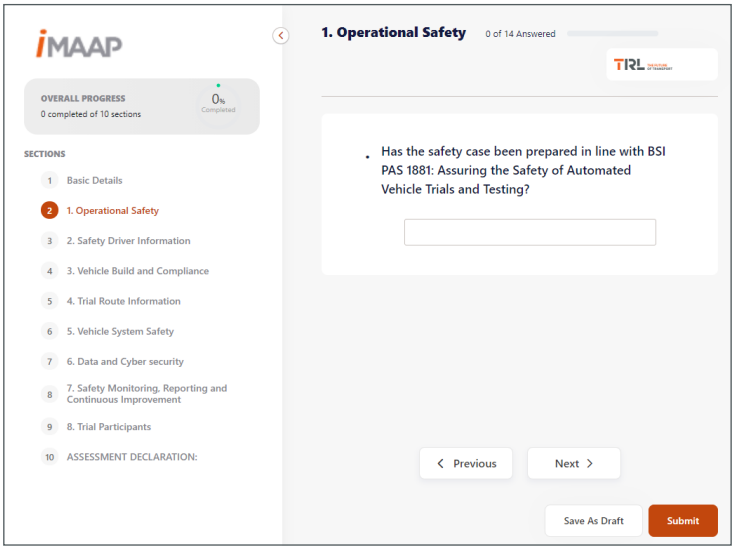
In subsequent meetings, evidence was provided that these actions had been undertaken and the Research Ethics Committee documented the approved phase 2 of the trial to proceed.

TRL services

TRL has significant safety assurance expertise which has been developed through experience in several CAV trials. Therefore, TRL are well-placed to support TOs in a variety of their safety assurance processes as described below. To find out more about our Team and the Services we offer, please email enquiries@trl.co.uk.

TRL Connected and Automated Mobility – Safety Assurance Tool (TRL CAM-SAT)

TRL led the build and set up of the Smart Mobility Living Lab (SMLL) in London, part of CAM testbed UK. One key activity within this was to develop a range of safety assurance procedures for the SMLL including an onboarding process for new CAV trials to the test bed.



Based on this experience, TRL have developed the TRL Connected and Automated Mobility – Safety Assurance Tool (TRL CAM-SAT) to support the safety assurance review, to ensure a consistent and simple approach to safety case and trial acceptance. The specifications for the tool were drawn specifically from the challenges identified during the consultation with stakeholders on safety assurance as part of Project Endeavour.

The tool provides a series of high level questions covering safety assessment criteria drawn from the DfT Code of Practice and PAS standards – to be completed by the trialling organisations. This enables the transfer of fundamental information regarding the proposed CAV trial to key stakeholders (e.g. local authorities and test beds) to aid understanding of the trial and support planning and approval of the trial.

Also include within the tool is:

- The ability to upload supporting documentation – avoiding the requirement for email dialogue – everything would be stored in the same place.
- An area for stakeholders (e.g. local authorities and test beds) to host information for CAV trialling e.g. any pre-requisites, policies and local information pertaining to the area/test-bad, that would assist TOs in the trial planning and safety case development.

Independent review of safety cases

TRL has previously developed and reviewed safety cases for a range of CAV projects including GATEWAY, Streetwise, DRIVEN and the HelmUK HGV platooning trials. TRL also co-authored BS PAS 1881 – Assuring safety for automated vehicle trials and testing as well as the latest Zenzic Safety Case Framework.

Based on this experience, we are ideally placed to provide TOs with independent safety assurance for CAV trials including:

- Independent review of entire safety cases
- Independent review of specific safety case elements (e.g., operational risk assessment, route safety assessment, emergency response plan, operational guidance).

Design or review of Safety driver training

TRL has developed and implemented safety operator training programmes for GATEWAY and HelmUK HGV platooning trials and has independently reviewed safety operator training programmes for DRIVEN and Streetwise. TRL is also currently authoring *PAS 1884 – safety operators in automated vehicle testing and trialling* (due to be published summer 2021).

We therefore have significant expertise and experience regarding the best practice requirements for operator selection, responsibilities and training, and can assist in the design and development of training programmes or by independently reviewing them.

Assistance with Research Ethics

TRL has extensive experience in conducting ethics impact assessments across a wide range of research studies including CAV trials such as GATEWAY, HelmUK HGV platooning trials and SMLL Shared Research Programme Trials.

We have a number of ethics trained representatives and have developed an extensive range of policies, procedures and documentation including:

- Research Ethics Policy
- Ethical Procedure for Research Involving Human Participants
- Ethical Principles and Guidance
- Ethics Approval Checklist and Application Form
- Participant Information Sheet and Consent Form
- Privacy Notice for Research Project/Study
- Data Protection – Personal and Sensitive Data Management

TRL can provide assistance to TOs in developing ethics impact assessment procedures and/or by participating in the review committee to help assess the ethical impacts of a trial.

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