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Contents

Summary

This pre-study examines the technological landscape, practical experience, and regulatory requirements related to in-vehicle detection of alcohol- and drug-impaired driving, focusing on alcohol and cannabis.

Current detection approaches fall into five categories: physiology-based systems (breath, sweat, biosignals), tissue spectroscopy, camera-based driver monitoring, vehicle kinematics, and hybrid systems. No single modality today offers sufficient specificity to reliably detect alcohol or drug impairment during real driving. Physiological sensing best reflects substance presence, but integration hurdles remain; behavioural sensing (oculomotor patterns, posture, vehicle control) reveals impairment but lack specificity. Hybrid systems that combine presence-based and behaviour-based indicators has the greatest potential.

Practical experience from prior intoxication studies carried out by the project partners highlighted key operational requirements. Reliable experiments depend on high staffing density, strict safety protocols, disciplined event logging, and carefully tuned alcohol dosing procedures. Recruitment is challenging and requires screening for health, medications, sleep patterns, and substance use history. Breath-based ground truth measures require rigorous protocols, and evidential-grade analysers are recommended in future studies. Closed-track environments remain necessary for safety but may not fully reflect real-world driving. Simulator extensions can complement realism. Across partners, there was strong alignment on experimental design for future alcohol studies, with growing interest in shifting focus toward cannabis impairment.

Conducting cannabis experiments in Sweden requires a full clinical-trial application through the EU CTIS system, reviewed by both the Medical Products Agency and the Ethical Review Authority. A medically responsible investigator and a compliant drug manufacturer must be secured before submission. Additional requirements include medical screening, on-site medical staff, blood and specimen handling procedures, and detailed documentation of the cannabis product. In addition, a separate government permit is needed because driving under drug influence is illegal even on closed tracks. Recruitment will be particularly challenging due to the illicit status of cannabis in Sweden, and the method of drug administration (vaporised, smoked, capsules, edibles) must be selected to balance safety, impairment dynamics, and sensor detectability.

Taken together, the project show that:

- Robust detection of alcohol and drugs will likely require multi-modal sensing and careful experimental design.
- SAFER partners already share substantial know-how for alcohol studies, but cannabis research introduces additional legal, medical, and logistical complexities.
- A future multi-partner cannabis study is feasible but will require early coordination with medical investigators, compliant manufacturers, and regulators, alongside realistic timelines for approvals and recruitment.

In-vehicle detection of alcohol and drug impaired drivers

1 Background

Driver impairment remains a major road-safety challenge. Around 20% of road deaths are linked to sleepiness (Bioulac et al., 2017; Williamson et al., 2011), and a similar proportion to alcohol (Vissers et al., 2017). The proportion of involved drivers who tests positive for cannabis fluctuates more between countries but is over 30% in the U.S. (Lira et al., 2021). These impairments can cooccur and amplify risk. For example, partial sleep deprivation combined with even low alcohol levels markedly degrades performance (Horne et al., 2003).

Regulation and assessment frameworks concerning driver monitoring systems are evolving but remain incomplete. In Europe, the General Safety Regulation[1] introduces requirements around driver drowsiness and distraction, and Euro NCAP's roadmap[2] considers driver engagement and impairment. As for alcohol and drugs, NHTSA has released an Advanced Notice of Proposed Rulemaking[3] that would require new vehicles in the U.S. to be equipped with advanced alcohol detection technology. Similarly, Euro NCAP's 2026 protocol[4] introduces a new scoring model, allocating 25 safety points to driver monitoring, with up to 2 points for detecting other impairments, such as alcohol, without relying on intrusive interlock devices.

In-vehicle systems could either detect impaired drivers before driving starts, during driving, or a combination of both. Nevertheless, non-intrusive, production-grade detection of alcohol and drugs (notably cannabis) using driver-monitoring sensors is still maturing and requires stronger datasets and evaluation procedures (Hayley et al., 2021). From a technical standpoint, camera-based Driver Monitoring Systems (DMS) are convenient since the sensor is already installed in most new vehicles, and they already measure ocular and facial behaviour relevant to impairment (Koch et al., 2023; Zemblys et al., 2024). However, many of these features are non-specific. Both sleepiness and alcohol intoxication slow saccades, lengthen blinks, and reduce scanning (Beirness et al., 1985; Donelson et al., 1985; Fransson et al., 2010; Schleicher et al., 2008; Tyson et al., 2021; Watling & Home, 2022; Zemblys et al., 2024). Acute cannabis use further alters ocular control and pupil reflex dynamics (Manning, Downey, et al., 2024). These overlaps and differences complicate attribution of cause from camera-based features alone and motivate multi-modal sensor modalities and careful validation.

State-of-the-art evidence guiding this work indicates that impairment signals depend not only on dose but also on time course and context. Behaviour can differ on the ascending versus descending limbs of the blood/breath alcohol curve (Mellanby, 1919), sleep pressure varies intra-individually, and cannabis effects depend on route of

[1] https://eur-lex.europa.eu/eli/reg/2019/2144/
[2] https://cdn.euroncap.com/media/74468/euro-ncap-roadmap-vision-2030.pdf
[3] https://www.govinfo.gov/app/details/FR-2024-01-05/2023-27665
[4] https://www.euroncap.com/en/for-engineers/protocols/2026-protocols/

administration, potency, and tolerance (Hartman & Huestis, 2013). Consequently, datasets must capture the temporal dynamics of the impairment (e.g., serial measurements, event marking), relevant confounders (light conditions, camera placement, learning/familiarity), and mixed states to support robust algorithm development and fair evaluation.

In summary, this project arose due to a clear safety need in combination with regulatory momentum and technical opportunity. By integrating partner experience, state-of-the-art findings, and permit pathways, this pre-study lays the groundwork for a larger multi-partner programme on non-obtrusive in-vehicle detection of alcohol- and cannabis-impaired driving.

2 Project set up

2.1 Purpose

The purpose of this pre-study was to prepare a robust foundation for a larger, multi-partner programme that advances in-vehicle detection of alcohol- and drug-impaired drivers. Specifically, the project aimed to:

- consolidate recent practical experience from closed-track and simulator studies to avoid repeated pitfalls in recruitment, dosing, operations, measurement, and analysis.
- produce a concise evidence synthesis of impairment indicators and evaluation procedures relevant to production-grade DMS.
- define the regulatory pathway and required approvals in Sweden for conducting ethically and legally compliant studies, particularly targeting cannabis.
- support the preparation of a larger joint project application that operationalises the planned experiments and accelerates development, testing, and validation of non-obtrusive, in-vehicle detection systems.

2.2 Objectives

The present SAFER Idea Exploration project responds to the identified needs by consolidating know-how from recent Swedish and international efforts and by preparing the practical foundation for larger, ethically and legally sound experiments. The objectives are to:

(i) review the state of the art across simulator and closed-track studies of alcohol and other drugs, and clinical impairment tests.
(ii) capture partners' lessons learned through a workshop.
(iii) map the permits and approvals required in Sweden for alcohol and, prospectively, cannabis studies.

2.3 Project period

The project was carried out between August 2025 and January 2026.

2.4 Partners

The project was a collaboration among SAFER partners and one external partner:

- VTI (co-ordinator): overall project coordination and administration.
- Magna International Inc.

- Smart Eye AB
- Volvo Car AB
- AB Volvo

External partner:

- RespiroCraft, a start-up specialising in THC detection in exhaled breath.

3 Method and activities

The project strived for efficient evidence synthesis and knowledge-sharing across partners rather than new data collections and scoping reviews.

The literature review was intentionally not a formal, protocol-driven systematic search and will inevitably miss important papers. Instead, we adopted a seed-and-snowball strategy that began with recent review articles. Measurement modalities that are either already used in vehicles or realistically integrable in the near term were prioritised.

To complement the desk work, we convened a partner workshop with the goal to encourage open sharing of practical lessons that typically remain within internal teams. This includes recruitment and screening practices, dosing protocols and safety management, on-site staffing and roles, and data-logging discipline and event marking. Scene-setting presentations by all partners were followed by discussions and open Q&A to capture practices, pitfalls, and recommendations for future studies.

Finally, the permits and approvals objective centred on contacting the responsible Swedish authorities and collecting guidance directly from official channels. This provided a practical roadmap of approvals, lead times, fees, and document granularity to underpin realistic planning for the next phase.

4 Results and Deliverables

It was decided to remove one of the objectives from the original application (to outline a feasible design for alcohol impairment data collections). During the workshop, all partners were essentially already aligned on how such an alcohol experiment should be designed and realised. Most interests were instead directed towards a future cannabis study, whose first steps are here covered in section 4.3.

4.1 State of the art review results

The literature survey spanned alcohol and drug detection technologies that can be used either before driving (like an alcolock) or while driving (like a driver monitoring system). This includes breath-based technologies (measuring alcohol in the cockpit air as a driver breathes normally), touch-based technologies (uses tissue spectroscopy to measure blood alcohol levels through the skin), camera-based technologies (eye tracking correlates of alcohol intoxication), and driving performance-based technologies (lane deviation or lateral variability). Note that presence signals (breath, spectroscopy) estimate alcohol/drug concentration, while functional signals (oculomotor, kinematics) reflect behavioural impairment. Both are useful because concentration does not perfectly map to impairment, and behavioural metrics are not substance-specific. A summary is provided in Table 1.

Table 1: Summary of measurement modalities for alcohol detection, including strengths, limitations, and production outlook.

Physiology (breath alcohol content, sweat, biosignals)	*Strengths*: direct alcohol presence via breath or sweat *Limitations*: passive breath sensing needs climate control system integration; sweat latency (≥ 90 min); biosignals are non-specific to alcohol; small samples and lab conditions predominate. *Production outlook*: Directed breath: production-ready (fleet); passive breath/sweat: advancing; biosignals: complementary since non-specific.
Tissue spectroscopy (NIR touch)	*Strengths*: estimates alcohol concentration directly; workplace devices available. *Limitations*: integration cost/size; user contact/gloves; automotive prototypes still under validation. *Production outlook*: anticipated licensing "in the next few years" once miniaturised and validated.
Camera	*Strengths*: widely available hardware. Different drugs affect oculomotor metrics in different ways. *Limitations*: specificity (sleepiness overlap), different drugs affect eye movements in different ways, hardware sensitivity, light sensitivity (especially if pupil-related metrics are used), cross-subject generalisation. *Production outlook*; first products have recently been launched, but there is limited information about their accuracy
Vehicle kinematics	*Strengths*: continuous, sensors already available. *Limitations*: poor specificity to alcohol (sleepiness, distraction confound); environment/driver baseline highly influential. *Production outlook*: suitable for behavioural monitoring, not for standalone alcohol detection.
Hybrid	*Strengths*: potential specificity gains (presence + behaviour). *Limitations*: integration, calibration, privacy/acceptance, sparse public algorithms, limited large-scale validation. *Production outlook*: most promising long-term route for in-drive alcohol detection, contingent on robust validation and standardisation

4.1.1 Measurement modalities

4.1.1.1 Physiology-based systems

Physiology-based systems assess a driver's bodily signals to infer impairment. Key sub-types include: (a) breath alcohol sensing (BrAC) using electrochemical/infrared

analysers, including cabin-integrated sensors aiming at passive sampling; (b) sweat/transdermal ethanol measurement via sensors integrated into the steering wheel or wearable patches; and (c) broader biosignals such as heart rate (HR/HRV), blood pressure (BP), respiration, and brain waves (electroencephalogram, EEG) ECG/EEG. Breath and sweat are the primary physiological measures for direct alcohol presence (Prendez et al., 2024).

- Breath Alcohol Content (BrAC; including direct breath or cabin vapour): Breath sensors are typically based on electrochemical/IR technologies. In practice, in-cabin passive systems must isolate the driver's breath plume, manage dilution, and sample repeatedly during the drive. There is ongoing development going from directed breath (commercial fleet) towards passive in-cabin BrAC sensing (Prendez et al., 2024). Quality and accuracy of these sensors are continuously improving (Zaouk et al., 2023).
- Sweat/transdermal ethanol: steering-wheel integrated sensors or patches detect ethanol via sweat. While promising in controlled settings, detection latency can be ≥90 min post-consumption (Yu et al., 2022), and glove use prevents sampling. Wearable sensors has been presented that are able to detect several different drugs in human sweat samples, including cocaine, heroin, MDMA, amphetamine-type stimulants, and new psychoactive substances (Liu et al., 2022; Zhang et al., 2022).
- Cardiovascular and other biosignals: acute alcohol tends to raise HR and alter HRV, and may transiently increase BP. However, these are non-specific (stress, exertion, workload, disease may trigger the same response), so they all have low specificity and cannot by themselves establish blood alcohol content (BAC) or the presence of other drugs.

4.1.1.2 Tissue spectroscopy-based systems

Near-infrared (NIR) tissue spectroscopy illuminates the skin with infrared light and measures the wavelengths of the reflected light. The alcohol concentration is determined from the interstitial fluid present under the dermal tissue layer (Ridder et al., 2009). The spectral features map directly to BAC (or a close proxy), offering high specificity to alcohol presence compared with behavioural measures. As for sweat-based sensors, this sensor requires user contact (i.e. no gloves). As such, tissue spectroscopy-based systems show strong specificity, but production viability dependent on miniaturisation and ergonomics (Prendez et al., 2024).

4.1.1.3 Camera-based systems

Camera-based Driver Monitoring Systems (DMS) use one or more inward-facing IR/RGB cameras (often IR for lighting robustness) to track eyes/eyelids, pupil, head/neck pose, face, and sometimes hands/feet/posture. Some systems also explore remote vital signs via imaging photoplethysmography. Camera features reflect behavioural changes rather than BAC per se. Their specificity to alcohol (vs. sleepiness/distraction) is limited without additional measures or context (Prendez et al., 2024).

Alcohol slows saccades and disrupts smooth pursuit, blink duration/closure often increases, horizontal gaze nystagmus is an established sign of alcohol intoxication but is rarely naturally expressed at high eccentricities in driving, pupillary light response (with a controlled light stimulus) can detect post-dose changes relative to an individual's baseline (Garrisson et al., 2021; Maurage et al., 2020; Prendez et al., 2024).

Similar oculomotor features are also used to detect drugs such as cannabis and methamphetamine (Hayley et al., 2024; Manning, Downey, et al., 2024). Face/posture/limb activity provides weaker signs of alcohol intoxication (Prendez et al., 2024), including facial relaxation, drooping features, grip looseness, altered hand/foot behaviour, and seat/posture cues.

Commercially available systems are currently being introduced on the market[5, 6]. These systems are claimed to estimate alcohol impairment from 0.5‰, but with higher accuracy for higher BAC. Generalisation is constrained by sensor placement, individual variability, and state overlap (sleepiness vs alcohol). Multi-camera DMS improve robustness (Zemblys et al., 2024), but specificity still requires additional modalities or strong context cues.

4.1.1.4 Vehicle kinematics-based systems

These systems use vehicle motion and driver inputs to infer impairment, including measures of speed, acceleration/braking, steering torque/angle/reversal, lane position, and sometimes headway.

Lane keeping and speed variability increases with intoxication. The related measures of steering reversal rate, steering entropy and within-lane deviation are also frequently used features. A meta-analysis highlight the standard deviation of lateral position (SDLP) as a consistent indicator, with an increase of 4.0 ± 0.5 cm under alcohol (Irwin et al., 2017). Production systems are often not based on SDLP, but rather on the residuals of a predicted path relative to the driven path.

Like other indirect measures of intoxication, vehicle-kinematic measures are sensitive but not specific (sleepiness, distraction, stress etc. also degrade kinematics). There is a dose-response relationship in controlled designs (Irwin et al., 2017; Lee et al., 2011), yet attribution to alcohol alone is unreliable without corroborating measures. It is essential that enough driving data is available before making a decision, and one must carefully consider the driving environment and sources of impairment when using these features (Miller et al., 2025).

Kinematics are already widely used as a general measure of driver impairment. Performance depends on environment, route, automation mode, and individual baseline (Prendez et al., 2024).

4.1.1.5 Hybrid systems

Hybrid systems fuse multiple modalities such as cameras + kinematics, cameras + physiology, or cameras + physiology + kinematics. This fusion of data from different modalities provides complementarity and consequently improved specificity (alcohol vs drowsiness/distraction). In research settings, the combination of cameras and kinematics is common (Deuber et al., 2025; Göbel et al., 2025), but there are also examples of combining passive breath sensors with cameras (Ljungblad et al., 2017).

Hybrids are the most plausible path to production-grade, specific detection because they combine presence and behaviour signals. However, deployment faces several

[5] https://www.smarteye.se/news/smart-eye-launches-first-ever-driver-monitoring-system-with-alcohol-impairment-detection/

[6] https://seeingmachines.com/seeing-machines-unveils-technology-to-detect-alcohol-impaired-driving/

hurdles such as complex hardware integration (multi-sensor), calibration, data quality, false alerts, user acceptance, and privacy. Robustness across drivers, vehicles, lighting, climate control system settings, weather, and mixed states (alcohol × sleepiness) still requires large-scale validation (Prendez et al., 2024).

4.1.2 Differences between alcohol and other drugs

Different drugs have different effects and consequently the physiological and behavioural response differs. Some of these differences are outlined below, based on a sub-grouping of drugs into the categories cannabis/THC, CNS depressants (benzodiazepines), opioids, and stimulants.

Alcohol use disorder reduce HRV (Cheng et al., 2019; Quintana et al., 2013), and acute alcohol consumption additionally also increase the heart rate (Chen et al., 2018). Similar effects can be seen for cannabis and stimulants, while depressants and opioids have the opposite effect (Chen & Ashburn, 2015; Hendrickson et al., 2021; Masini et al., 2020; Stone et al., 2015).

Alcohol breath sensing is getting ready for vehicle use, but for other drugs, breath is currently at the stage of "collect-and-send-to-the-lab" (Johnson-Davis et al., 2025). Sweat-based sensing is gradually becoming better, and the main disadvantage of long time lags is gradually getting better (~20 minutes, Brobbin et al., 2023). Importantly, sweat sensing is not limited to alcohol but can also detect methadone, methamphetamine, amphetamine, tetrahydrocannabinol etc. (Childs et al., 2024; Xue et al., 2020).

As for vehicle kinematics, there is a dose-related increase in SDLP for alcohol (Hartman et al., 2015). For benzodiazepines, simulator studies show impaired lane keeping, speed control and steering (Stone et al., 2015). For stimulants, low doses may transiently improve certain task components, but do not offset fatigue-related driving impairment (Hjälmdahl et al., 2012).

Across drug classes, eye metrics show characteristic changes. Cannabis alters gaze and pupil dynamics, especially pupil size variability (Haider et al., 2024). Stimulants (methamphetamine) increase fixation rate/duration and produce less dispersed, more disorganized visual scanning even when basic lane-keeping is preserved, which is different from low-dose alcohol that degraded both oculomotor control and driving performance in the same study (Hayley et al., 2024). Benzodiazepines reliably slow saccadic peak velocity and reduce smooth-pursuit gain in a dose-dependent manner (Ettinger et al., 2018; Roy-Byrne et al., 1993). Opioids cause miosis and strongly suppress pupillary unrest in ambient light (McKay & Larson, 2021).

4.1.3 Individual variability and context

Individual variability in oculomotor behaviour is a central confound. There are large normative ranges in classic metrics such as horizontal gaze nystagmus and smooth pursuit, with effects of age, stimulus/background parameters, and medical conditions that can mimic or mask drug signatures if protocols are not standardized (Rubenzer & Stevenson, 2010). As previously mentioned, benzodiazepines reliably reduce saccadic peak velocity and smooth-pursuit gain, but broader saccadic parameters can show sex-dependent changes, cautioning against one-size thresholds without baselining (Roy-Byrne et al., 1993). For opioids, pupillary unrest in ambient light declines consistently and profoundly under remifentanil, outperforming static diameter and several reflex metrics (McKay & Larson, 2021), but its level changes with age (decreasing as you get

older) and other factors such as pain, vigilance, and diabetes (McKay et al., 2024; Regen et al., 2013).

Driving environment and measurement context add further variance. On-road eye-tracking shows that day/night and road class reshape "normal" gaze. At night and on motorways vertical/horizontal dispersion narrows, while residential streets elicit broader lateral scanning toward potential hazards, implying that gaze distributions are highly situational and must be modelled with context (Kunst et al., 2025). These environmental shifts can rival drug effects in magnitude, reinforcing the need for within-subject baselines and context-aware models.

Finally, non-target pharmacology and physiology can confound camera features. Sedating antihistamines (e.g., diphenhydramine) slow saccades and increase latency without necessarily impairing smooth pursuit or memory (Hopfenbeck et al., 1995), potentially mimicking benzodiazepine effects on saccadic velocity if medication history is unknown.

4.1.4 Summary

No single modality is sufficient today for specific in-drive alcohol detection at scale. In the review report by NHTSA, Prendez et al. (2024) finds no commercially available product capable of estimating alcohol presence/impairment during driving solely via DMS (camera/behaviour), and they encourage data fusion solutions.

Individual variability and context are major performance drivers (subject-specific models outperform population models; performance varies by roadway and lighting). Careful calibration/personalisation, context awareness, and multi-sensor fusion are required.

Impairment vs alcohol content: The blood alcohol concentration provides legal thresholds but do not perfectly map to impairment. Functional measures (camera/kinematics) capture impairment but lack specificity to alcohol without physiological inputs.

4.2 Workshop results

The aim of the workshop was to share practical know-how about planning and running data collections with alcohol- and drug-impaired drivers. The session brought together colleagues from VTI, Volvo Cars, Volvo Group, Smart Eye, Magna, and Respirocraft to compare designs, discuss permits and ethics, stress-test recruitment and dosing strategies, sketch the outline of a 'near-perfect' multi-partner study, and gauge interest in a future joint grant proposal.

4.2.1 Permits, ethics, and insurance (in Sweden)

VTI described the current government permit (valid to 2034), which limits experiments to closed test tracks with dual-control vehicles and trained safety drivers, sets a maximum speed (80 km/h), and requires prior ethical approval. VCC holds a similar permit.

Ethical review typically needs to be submitted at least six months in advance (informally indicated by the Swedish Ethical Review Authority, EPN) to allow for one or two rounds of revisions. It should be noted that very similar protocols can receive different decisions across subcommittees.

For VTI, participant insurance is handled through Kammarkollegiet. Recent changes in their procedures mean more elaborate submissions (similar to the research plan sent

to EPN), longer handling, and higher cost. Cover is limited to the experimental period on site and the journey to/from the facilities. If a participant remains intoxicated after leaving the site, they are uninsured during the sobering-up period. VCC only used employees as participants which solved their insurance issues.

4.2.2 Staffing and operations on the day

Successful experiment days depend on high personnel density focused on safety and participant well-being: a safety driver (operating the dual control), test leaders, data-logging technicians, and preferably a nurse on site. On-site project lead is also advantageous, especially early in the data collection campaign. With parallel participants, it helps to add a 'party-room' host for the drink session, a dedicated car team, and spare rooms for recovery or debriefing. Group-chat updates kept everyone aligned, but chats tend to become messy after a while, why general updates to the study procedures must be communicated by some other means as well. VCC arranged taxis both ways for all participants in their intoxication experiments, with individual rides home after intoxication runs. This solution was not accepted by the Ethical Review Authority for VTI, where each participant had to be collected by a friend or relative who signed a form to take responsibility until the participant was fully sober.

Ensuring enough driving time per condition (around twenty minutes worked well) supports analysis. Keeping a dedicated car team protects data quality. Using digital, in-drive logging by the test leader to mark events simplifies later alignment.

4.2.3 Recruitment realities

Recruitment takes time and resilience. Late drop-outs are common, evening slots and weekends tend to attract greater availability, and targeted adverts aimed at women still draw predominantly male volunteers. Screening includes AUDIT and interviews with all candidates to identify potential alcohol problems. Recruiting friends who participate in parallel can create a more relaxed atmosphere and a better 'party vibe' during consumption.

Recruitment should aim for a balanced gender distribution and include evening and night sessions to facilitate analyses of confounding effects with sleepiness.

4.2.4 Inclusion/exclusion criteria and study procedures

Volvo Cars shared pragmatic criteria balancing scientific control with safety. Inclusion required employment at VCC for insurance reasons, BMI 19–30, regular sleep, ≥5,000 km/year, 'social drinking' within defined weekly bands, and a category B licence. Exclusions included medications contraindicated with alcohol, motion-sickness tendency, professional drivers, ongoing/past substance misuse, a positive drug test, or a licence revoked for DUI. Operationally, the studies run a sober baseline drive, a controlled drinking session (vodka over 45–60 minutes, followed by a mouth rinse), and then the intoxicated drive with a safety driver. Directions around the track were counterbalanced, speeds are capped (50 or 70 km/h depending on segment), and debrief plus food precede taxis home. Similar criteria have been used by Smart Eye and VTI with volunteer participants.

4.2.5 Alcohol dosing

For dosing, VTI starts from the Hume–Weyers formula (gender, height, weight) and then tunes in practice (Hume & Weyers, 1971). A common pattern is to deliver roughly two-thirds first, then top up in smaller fractions to reach the target BrAC (often ≳1.0

‰). VCC used 40% alcohol with an indicative volume ≈ body-weight × 0.375 cl, capped at 40 cl, and adjusted women's doses by −2 cl.

Variability should be expected, women in particular showed greater spread. A lesson learned was to include additional factors, such as gastric bypass surgery, as exclusion criteria.

Several participants could not complete intoxicated drives (~10% in VCCs trials). Behaviour differed markedly on the ascending versus descending limbs (Mellanby effect, see Mellanby (1919)).

BAC is a blunt proxy for behaviour: drivers at the same BAC can display very different observable and behavioural signs.

For much higher targets (>~1.2 ‰), volunteers with 'typical' drinking habits often become ill; recruiting people with alcohol dependence would raise ethical concerns but may be necessary if such levels are desired. Selecting the target BrAC/BAC must balance scientific gain and participant well-being.

4.2.6 Measurement choices: BrAC, BAC, and impairment

Breath testing requires careful protocol discipline: waiting after drinking, mouth rinsing, and clear blowing instructions. A single blood-to-breath conversion factor (e.g., 2100:1) can misestimate true BAC, particularly at higher concentrations (Hartung et al., 2016).

Evidential devices such as the Evidenzer, and where feasible, blood sampling, provide more robust ground truth.

Crucially, BAC/BrAC alone does not capture impairment: pairing BrAC with behavioural measures such as lane keeping, reaction time tests, and simple secondary tasks yields a truer picture, and analyses should note whether measurements are on the ascending or descending limb. It was observed that several Dräger handheld devices produced different within-subject readings even directly after calibration; evidential analysers may provide more robust results.

4.2.7 Closed tracks versus real roads

Tracks are static with few or no other road users. Weather cannot be fully controlled, but vibrations and lighting are realistic. We debated whether closed-track data are 'good enough' for the intended algorithm development, and, importantly, which real-world crash contexts to prioritise: when intoxication-related crashes typically occur, how far drivers travel before an incident, and what conditions are most common and should be replicated in data collections. The consensus was to keep pushing track realism and to complement measurements with simulator scenarios covering risky conditions that would be unethical on public roads. No one advocated taking intoxication experiments onto public roads. A common limitation in all controlled experiments conducted in the group was that a safety driver was ever-present, which may affect the participants behaviour.

4.2.8 Device classification, liability, and evidential equipment

A recurring theme was to avoid solutions that would classify in-vehicle driver-state hardware as a medical device, with the attendant MDR compliance, certification, recalibration, and liability implications. This does not preclude collaboration with medical-grade equipment off-board. For alcohol ground truth, evidential breath analysers that comply with international standards were highlighted as a better option

than screening-grade handhelds when practicable (the Evidenzer device was mentioned several times).

4.2.9 Safety interventions when the driver is impaired or unresponsive

The group discussed how driver-monitoring outputs could inform vehicle behaviour beyond warnings. Ideas included adapting forward-collision and lane-keeping strategies when impairment is detected, escalating warnings, and if the driver becomes unresponsive triggering a controlled safe stop. This aligns with the direction of travel in current and forthcoming safety-assessment protocols that reward detection of impairment and robust unresponsive-driver responses (sudden sickness).

4.2.10 Practical note: language and access in professional-driver studies

Interview-based studies with international lorry drivers proved challenging due to language and cultural barriers. To obtain reliable self-reports and context, teams may need staff fluent in relevant languages (e.g., North-African languages) to ensure mutual understanding and participant trust.

4.2.11 Breath THC screening and emerging challenges

Respirocraft presented an electronic-nose breath analyser aimed at rapid, non-invasive screening of recent cannabis use. THC in breath occurs at parts per trillion and degrades quickly, so the detection window in breath is short (hours), while oral fluid extends to roughly a day, blood much longer depending on use, and urine detects metabolites rather than current impairment. Synthetic cannabinoids and diverse consumption modes (edibles, oils, vapes) complicate the link between detection and impairment.

4.2.12 Additional information

Recent fact sheets from the International Council on Alcohol, Drugs & Traffic Safety (ICADTS) consolidate experimental findings that THC-containing cannabis impairs driving soon after use, with impairment at about forty minutes comparable in magnitude to that of drivers at approximately 0.5 ‰, declining substantially by four hours; CBD alone does not appear to impair when consumed on its own. Swedish law sets per-se drunk-driving thresholds at 0.2 ‰ BAC (or 0.10 mg/L BrAC) and aggravated drunk driving at 1.0 ‰ BAC (or 0.50 mg/L BrAC). For illicit drugs not prescribed by a physician, Sweden applies a zero-tolerance approach via blood testing.

Sativex (nabiximols; THC+CBD) is an oromucosal spray approved in Sweden for MS-related spasticity and is narcotic-classified.

Research comparing venous BAC and BrAC shows that the blood-to-breath conversion factor varies considerably, especially at higher BAC, cautioning against reliance on a single fixed ratio.

- ICADTS Cannabis & Driving Fact Sheets: https://www.icadtsinternational.com/Fact-Sheets
- Swedish Transport Administration (Trafikverket) — drunk driving limits: https://www.trafikverket.se/resa-och-trafik/trafiksakerhet/sakerhet-pa-vag/alkohol-och-narkotika-i-vagtrafiken/vad-sager-lagen-om-rattfylleri/
- Swedish Medical Products Agency — CTIS fees (SE): https://www.lakemedelsverket.se/sv/tillstand-godkannande-och-kontroll/klinisk-provning/lakemedel-for-manniskor/avgifter-for-klinisk-provning

- European Medicines Agency — CTIS overview: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-information-system
- Läkemedelsverket — Sativex information page: https://www.lakemedelsverket.se/sv/sok-lakemedelsfakta/lakemedel/20210224000074/sativex-munhalespray
- Euro NCAP — Safe Driving: Driver Engagement Protocol (v1.0, 2025): https://www.euroncap.com/media/85854/euro-ncap-protocol-safe-driving-driver-engagement-v10.pdf

4.3 Permits and approvals needed for a Swedish cannabis study

Given the workshop consensus that cannabis studies will be central to future work, this section outlines the regulatory pathway for conducting such studies in Sweden.

To conduct a cannabis study in Sweden, obtaining a permit for a clinical trial is required. Additionally, if the experiment is carried out on a test track rather than in a simulator, a permit from the government is also needed.

4.3.1 Application for a clinical trial permit

Clinical trial permits are granted following assessment by the Swedish Medical Products Agency (MPA) and the Ethical Review Authority. The content of this chapter is based on information obtained from the Swedish MPA's webpages and on insights from a previous simulator study conducted at VTI with drivers impaired by the medicinal drug dextroamphetamine (Hjälmdahl et al., 2012). This study was part of the EU project DRUID.

The application is submitted through CTIS (Clinical Trials Information System), a common web portal for clinical trials in the EU. After receiving the application, the Swedish MPA forwards the relevant documents to the Swedish Ethical Review Authority. Thus, only one submission is needed.

The application consists of two parts: one EU-common (Part I) and one national (Part II). It can be written in Swedish or English, but some sections must be in Swedish. Once submitted, the application is first validated, which can take up to 10 calendar days. If the application is deemed valid, both parts are reviewed within 45 days. If the application cannot be approved, the sponsor (the organization responsible for the study) will have up to twelve days to complete the application. After that, the review organization will have another 24 days to notify a decision. The conclusion can be: acceptable, acceptable with conditions, or not acceptable.

The application fee when Sweden is the concerned Member State is currently SEK 71,000, of which SEK 16,000 covers the Ethical Review Authority's processing. The Swedish MPA may grant a fee reduction in exceptional cases. In the DRUID trial, the application was exempt from the fee.

The two parts of the application consist of the following:

Part I:

- Cover letter
- EU application form
- Protocol with synopsis

- Investigator's Brochure
- Good manufacturing practice (GMP) for investigational and auxiliary medicinal products
- Investigational and auxiliary medicinal product dossiers
- Scientific advice and pediatric investigation plan
- Labelling

Part II:

- Recruitment arrangements
- Information for subjects, including the consent form
- Suitability of the investigator
- Suitability of the facilities
- Insurance cover or indemnification
- Financial and other arrangements

The content largely overlaps with that of an ethical approval application for a simulator or test track study that does not involve drugs. Additional content includes descriptions of the drug itself (such as its composition and manufacturing process) and potential side effects. There are also specific documentation and archiving requirements that the sponsor must comply with.

A clinical trial conducted on humans must be led by an investigator who is medically responsible for the trial. The investigator should be a qualified medical doctor with sufficient expertise in the relevant area. In the DRUID trial, the head of the Addiction Clinic at US Linköping served as the investigator.

4.3.2 Cannabis, method of use and manufacturer

Cannabis contains numerous bioactive compounds, of which tetrahydrocannabinol (THC) and cannabidiol (CBD) are the most well-studied. The primary intoxicating component is THC, and its impairing effect depends on factors such as dose, method of use, and previous experience with drugs. Previous research, summarized in ICADTS (n.d.), also shows that THC consumption can impair driving ability, whereas CBD alone does not appear to have such an effect. Thus, THC is the compound to consider when determining the dose and method of intake.

Cannabis can be smoked, vaporized, or ingested through capsules or edibles. The method of administration can influence the level of impairment, recovery time, and the ability of different sensors/methods to detect the drug. It is therefore important to choose the method of use carefully. Previous on-road and simulator studies have employed various administration methods, such as smoking (Brooks-Russell et al., 2021; Fares et al., 2022), vaporizing (Arkell et al., 2020), and ingestion via capsules (Schnakenberg Martin et al., 2023). One study in Australia tested medical cannabis where participants consumed their own prescribed product (Manning, Arkell, et al., 2024).

The next step is to identify a compliant manufacturer for the selected cannabis product. In the DRUID trial, the medicinal drug was purchased from Apoteket Produktion & Laboratorier AB, which manufactured tablets containing dextroamphetamine and placebo and also provided the documentation required for the

clinical trial application. Establishing an agreement with a compliant manufacturer therefore greatly facilitates the application writing process.

4.3.3 Participant recruitment

Previous trials have recruited participants with prior experience of cannabis use, although the extent of this experience has varied from occasional to daily use. Prior experience can influence how participants respond to the drug, and it may also make them feel more comfortable if they know how they typically react. However, recruiting participants with prior experience will be challenging in Sweden, where cannabis use is prohibited and medical cannabis is rare. Participation in the study could imply unlawful behaviour. Careful consideration is therefore needed when planning the recruitment process.

4.3.4 Medicinal procedures before and during the trial

The study will involve medical procedures, including examinations and specimen collection, both before and during the trial. In the DRUID study, the following procedures were conducted:

- Pre-experiment screening: Participants underwent a medical examination covering psychiatric status, potential substance dependence, heart and lung examination, and neurological status.
- On the day of the experiment: A urine drug test was performed to confirm sobriety. In addition, blood samples were collected throughout the experiment to determine dextroamphetamine concentrations. Blood pressure and pulse were also registered on several occasions.
- Post-experiment follow-up: A follow-up meeting was held with participants a few weeks after the experiment for a medical check-up and to give them an opportunity to reflect on their experience. During this visit, a hair sample was collected to test for dextroamphetamine as an additional part of the study.

To ensure the safety of participants and facilitate specimen collection, at least one nurse was present throughout the trial, and the medically responsible doctor remained on call. Blood samples were analysed by the Swedish National Board of Forensic Medicine (RMV).

4.3.5 Permit from the government

In Sweden, it is illegal to drive while drowsy or intoxicated by alcohol or drugs, even on a closed test track. Exceptions can be granted only through a government-issued permit. Currently, VTI and VCC hold permits to conduct trials with alcohol-intoxicated drivers on a test track. VTI also has a permit to test drowsy drivers both on a test track and on public roads with other traffic. These permits have certain conditions, such as requiring vehicles to be equipped with dual control and ensuring that a trained safety driver accompanies the test driver. However, the permits do not cover drug-impaired drivers. To conduct a cannabis study in a real vehicle on a test track, an application must be submitted to the government. When the government receive the application, they consult relevant authorities, such as the Swedish Transport Administration, before making a decision.

4.3.6 Summary

The steps needed to obtain permits for a cannabis study are summarized in Figure 1. The first step is to establish collaboration with medical experts and find a medical doctor to serve as the study's investigator. An agreement with a drug manufacturer must

also be in place before submitting the clinical trial permit application, as detailed information about the drug is required. Applying for a government permit is a separate process that can be carried out in parallel with the other activities.

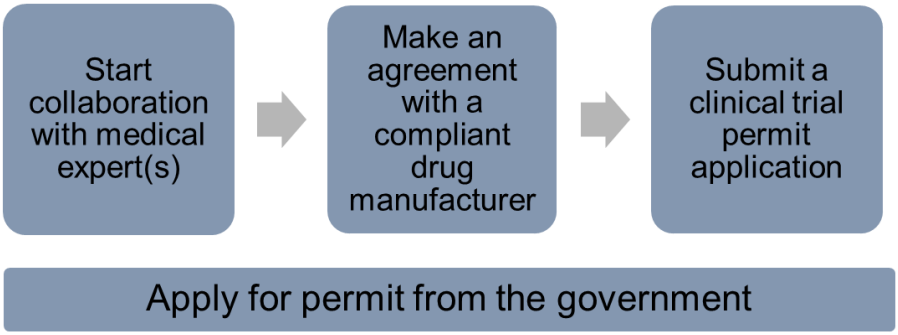

Figure 1 Overview of the process.

In addition to the design of the experiment at large, the following cannabis-related aspects need to be defined and agreed upon:

- Types and dosages of cannabis
- Inclusion and exclusion criteria for participants, with particular focus on prior cannabis experience and recruitment strategies
- Insurance requirements (Kammarkollegiet)
- Procedures for storing cannabis and blood samples during transport and at the trial facility
- Selection of a laboratory for blood sample analysis
- Process for hiring medical staff (e.g., nurses) for the trial

5 Conclusions, Lessons Learnt and Next Steps

This pre-study consolidated the state of the art on in-vehicle detection of alcohol- and drug-impaired driving, aligned partner experience from Swedish simulator and closed-track efforts, and clarified practical pathways for future work. The literature review and workshop converged on a clear message: no single modality is sufficiently specific for alcohol/drug detection in production. Hybrid approaches that combine alcohol/drug presence measures (such as passive breath sensing) with functional indicators (oculomotor/kinematics) appears to be the most promising route. In parallel, the project mapped the Swedish regulatory landscape and pinpointed concrete operational requirements (staffing, safety, dosing, measurement discipline) needed to run reliable, ethically robust studies.

Pragmatic inclusion/exclusion criteria are essential to balance safety, ethics and data quality. Effective criteria used by partners included recent driving exposure, BMI and general health limits, exclusion of medications contra-indicated with alcohol, and screening for motion sickness and substance misuse. Operationally, a sober baseline followed by a controlled dosing protocol and dual-control vehicles with a safety driver proved reliable. Sufficient drive time per condition (~20 min), disciplined event logging, and dedicated “tech teams” protected data integrity, while practicalities such as taxis/home escorts, on-site medical competence, and clear debrief procedures supported participant well-being.

A prospective Swedish cannabis study requires a clinical-trial application via CTIS (review by the Medical Products Agency and the Ethical Review Authority), led by a medically responsible investigator and supported by compliant manufacturing/labelling documentation for the THC product. If any on-track driving is planned, a separate government permit is required (in addition to ethics), and insurance arrangements must be in place. Lead times, fees, and document granularity are non-trivial. Recruitment will be sensitive given Sweden's legal context, and method of administration (vape/capsule/edible) should be chosen with both impairment dynamics and sensor detectability in mind.

Several partners have expressed interest in pursuing a Swedish cannabis study, starting in laboratory and simulator settings with future closed-track testing in mind. An already funded FFI project (SENSE) will investigate and apply for the necessary permits. The joint follow-on project will execute the actual experiments, provided that all required permits are granted.

6 Dissemination and Publications

Results and lessons were disseminated indirectly to the project partners via two channels: (i) this Final Report, and (ii) the dedicated project workshop. Together, these activities reached the intended audience—the core Swedish target group for in-vehicle alcohol/drug impairment detection (i.e., research institutes, OEMs, Tier-1 suppliers, and DMS technology providers).

No peer-reviewed publications or public datasets were produced within the project timeframe.

7 Acknowledgement

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