



Driving Innovation in Crisis Management
for European Resilience



D913.13 – ETHICAL MONITORING REPORT

SP91 - PROJECT MANAGEMENT

JUNE 2018 (M50)



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The DRIVER+ project

Current and future challenges, due to increasingly severe consequences of natural disasters and terrorist threats, require the development and uptake of innovative solutions that are addressing the operational needs of practitioners dealing with Crisis Management. DRIVER+ (Driving Innovation in Crisis Management for European Resilience) is a FP7 Crisis Management demonstration project aiming at improving the way capability development and innovation management is tackled. DRIVER+ has three main objectives:

1. Develop a pan-European Test-bed for Crisis Management capability development:
 - a. Develop a common guidance methodology and tool, supporting Trials and the gathering of lessons learnt.
 - b. Develop an infrastructure to create relevant environments, for enabling the trialling of new solutions and to explore and share Crisis Management capabilities.
 - c. Run Trials in order to assess the value of solutions addressing specific needs using guidance and infrastructure.
 - d. Ensure the sustainability of the pan-European Test-bed.
2. Develop a well-balanced comprehensive Portfolio of Crisis Management Solutions:
 - a. Facilitate the usage of the Portfolio of Solutions.
 - b. Ensure the sustainability of the Portfolio of Solutions.
3. Facilitate a shared understanding of Crisis Management across Europe:
 - a. Establish a common background.
 - b. Cooperate with external partners in joint Trials.
 - c. Disseminate project results.

In order to achieve these objectives, five Subprojects (SPs) have been established. **SP91 Project Management** is devoted to consortium level project management, and it is also in charge of the alignment of DRIVER+ with external initiatives on crisis management for the benefit of DRIVER+ and its stakeholders. In DRIVER+, all activities related to Societal Impact Assessment are part of SP91 as well. **SP92 Test-bed** will deliver a guidance methodology and guidance tool supporting the design, conduct and analysis of Trials and will develop a reference implementation of the Test-bed. It will also create the scenario simulation capability to support execution of the Trials. **SP93 Solutions** will deliver the Portfolio of Solutions which is a database driven web site that documents all the available DRIVER+ solutions, as well as solutions from external organisations. Adapting solutions to fit the needs addressed in Trials will be done in SP93. **SP94 Trials** will organize four series of Trials as well as the final demo. **SP95 Impact, Engagement and Sustainability**, is in charge of communication and dissemination, and also addresses issues related to improving sustainability, market aspects of solutions, and standardization.

The DRIVER+ Trials and the Final Demonstration will benefit from the DRIVER+ Test-bed, providing the technological infrastructure, the necessary supporting methodology and adequate support tools to prepare, conduct and evaluate the Trials. All results from the Trials will be stored and made available in the Portfolio of Solutions, being a central platform to present innovative solutions from consortium partners and third parties, and to share experiences and best practices with respect to their application. In order to enhance the current European cooperation framework within the Crisis Management domain and to facilitate a shared understanding of Crisis Management across Europe, DRIVER+ will carry out a wide range of activities. Most important will be to build and structure a dedicated Community of Practice in Crisis Management, thereby connecting and fostering the exchange of lessons learnt and best practices between Crisis Management practitioners as well as technological solution providers.

Executive summary

This report is the third Ethical Monitoring Report delivered in the DRIVER+ project. It aims to describe and reflect issues relating to research ethics that PRIO as leader of WP913 *Research Ethics & Societal Impact Assessments* is responsible for addressing. In general, the report follows a similar setup as the two previous reports, but some changes have also been implemented based on lessons learned from writing the previous two. These changes mainly pertain to decisions taken to make the process of screening the project in preparation for this report, more efficient and effective.

Based on the insights informing this report (derived from various sources explained in Section 1.2), no critical issues relating to research ethics have been identified for the DRIVER+ project, but some issues need follow up. These are described throughout this report. The implementation of GDPR as of 28/05/2018 is given focus in this report. Although the implementation of the GDPR represents a challenge for each individual partner, the responsibility for ensuring legal compliance from a business point of view lies with each legal entity / project partner. PRIO is neither responsible nor capable of ensuring GDPR compliance for all DRIVER+ partners. While PRIO is tasked to assist in specific cases or with specific questions, the responsibility of PRIO is mainly to ensure that the personal data collected, processed and shared within / by the project are handled in such a way that it protects the privacy of the data subjects. These data subjects are e.g. volunteers participating in the Trials or external solution providers. Based on a review of the GDPR, as well as consultations with the ESAB, the most relevant issues to be taken into account (which will also be summarized and shared with the full consortium) can be found in Section 4.

The report is structured around five main sections. The introductory section describes the fundamental importance of research ethics, and puts this report into the larger context. It also states the limits and sources of this report. Section 2 describes the implications of the GDPR on DRIVER+ and WP913 *Research Ethics and Societal Impact Assessments*. Section 3 is specifically about research ethics in the context of the DRIVER+ Trials, and also provides an update on the integration of Societal Impact Assessments (SIA) and research ethics into the Trial Guidance Methodology. Section 4 reports from the third meeting of the DRIVER+ Ethical and Societal Advisory Board, while Section 5 provides the current status of the plans for revision of the SIA framework and the plan for the SIA trainings.

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List of Acronyms

Acronym	Definition
AB	Advisory Board
DoW	Description of Work
DPIA	Data Protection Impact Assessment
DR	Dry Run
ESAB	Ethical and Societal Advisory Board
GDPR	General Data Protection Regulation
PM	Person month
SIA	Societal Impact Assessment
SP	Subproject
TGM	Trial Guidance Methodology
W0	Workshop 0
WP	Work package

1. Introduction

This deliverable is part of T913.3 *Ethical Monitoring*, which aims to monitor and systematically screen the project with regards to emerging ethical issues, and address and report on these in annual Ethical Monitoring Reports. D913.13 is the third out of four Ethical Monitoring Reports (the last report is due in M62), and it follows a similar structure as the first two reports (D95.31 *Ethical Monitoring Report 1*, which was submitted in M12, and D130.42 *Ethical Monitoring Report 2*, which was submitted in M24) (1) (2). The current report contains some repeated material from the second report, due to the fact that new partners and new constellations of partners have undertaken or will undertake new activities within or following the reporting period. A link to the submitted report on the CoW will be distributed to the consortium, including a reminder of PRIO's support task with regards to research ethics issues. In the Ethical Monitoring Questionnaires informing this report, it has also been suggested that reminders are sent to the consortium once in a while, reminding them also to re-read the ethics guidelines prior to specific activities (such as solution selection).

Since the second Ethical Monitoring Report was submitted, a lot has happened within DRIVER+. Although this report will not reflect upon these changes in general, a few key activities relevant to the scope and purpose of the report should be mentioned. First, the DRIVER+ Ethical and Societal Advisory Board had its first meeting after the suspension of the project was lifted. Some reflections from the meeting can be found in Section 4, and the full minutes will be later published as D913.51 *Minutes from the ESAB meeting 3 and 4 in M52*¹. Furthermore, the deliverable containing the third round of collected ethics approvals/notifications was submitted in M44 (D913.11 *Ethical Approval 3*) (3). Some key results from this deliverable are described in Section 3 in the following deliverable. Third, the general data protection regulation (GDPR²), which is part of the EU data protection reform package, came into effect (largely across Europe) on the 25/05/2018. In Section 2 of this deliverable, the key implications and relevance for the GDPR on DRIVER+ activities are described. A key distinction between the new rights of data subjects and requirements for businesses should already be mentioned. This can be summed up as follows: The ethical component in DRIVER+ (e.g. as it is currently developed as part of the Trial Guidance Methodology) will not be aimed at assisting *businesses* in adapting to the GDPR, but it will first and foremost take into account the *rights of the data subjects* who are potentially participating in the Trial activities.

1.1 The Fundamental Importance of Research Ethics³

In DRIVER+ we adopt a basic definition of research ethics: the application of moral rules and professional codes of conduct to the collection, analysis, reporting, and publication of information about research subjects, in particular active acceptance of subjects' right to privacy, confidentiality, and informed consent (4). While this slightly restrictive and more practically oriented definition is cited from the DRIVER+ Terminology, in the even wider sense, research ethics also includes the responsibility for the wider societal

¹ However, a request is being made to postpone the submission of this to M56, since the plan is to have a joint ESAB/AB meeting during Trial 2 in October.

² Regulation (EU) 2016/679 — protection of natural persons with regard to the processing of personal data and the free movement of such data. Available at: http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG.

³ This section is a revised (partly reiterated) version of section 1.1. of D130.42. The general content is still very much valid, and forms the basis for both this deliverable and the overall task that PRIO is responsible for in the project.

impacts of the research⁴. A more extensive definition understands research ethics as a broad set of standards, values and institutional arrangements that contribute to constituting and regulating research activities. These include the duty of honesty in research as well as responsibility to colleagues, other people, animals, the environment and society in the widest sense (5). From the beginning of the project, the main concern of research ethics in DRIVER+ is not only to conform to given legal and moral codes, but ultimately also to enhance the legitimacy and scientific quality of the project. The basic guidelines for fulfilling the most common research ethics obligations can be found in D91.3 *Ethical Procedures, Risks and Safeguards* (resubmitted in M22) (6), but updates to these guidelines- relating to both the progress of the project activities as well as the implementation of the GDPR- are also provided in this report.

The key ethical principles relevant for DRIVER+ are described in part B4 of the DRIVER+ DoW, and issues involved will be documented and addressed in the periodic Ethical Monitoring Reports. The basic premise for these reports, as well as the need for attentiveness with regards to research ethics in the first place, is the fact that research ethics fundamentally refers to the need to govern the impact (both positive and negative) that research can have on the society. The formal side of research ethics is about finding good ways to incorporate and integrate rules, regulations and “best practises” for how to include these conditions in the very fabric of the research activities on a fundamental level. In terms of application, research ethics concerns everyone involved in the research activity; e.g. funders, researchers, human research subjects and bystanders. For the DRIVER+ Trials, this means that e.g. both observers and players during the Trials are to be considered data subjects.

The DRIVER+ project involves the collection, processing and storage of data derived from individuals, both from members of the DRIVER+ consortium and individuals that are not formally part of the project. At the very core of research ethics are rules and guidelines for the participation of human subjects in research activities, which refer to the standard European Commission research ethics. The principles of the European Convention of Human Rights, the rules of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data⁵, and repealing Directive 95/46/EC (General Data Protection Regulation), must be strictly upheld at all levels when addressing ethical questions and issues within DRIVER+.

1.2 Sources of information for the Ethical Monitoring Report

Similar to the first Ethical Monitoring Report (D95.31) (1) and the second (D130.42) (2), the input to this report is derived from different sources:

⁴In DRIVER+, following the restructuring of the project during the suspension period, the task of monitoring and giving guidance with regards to research ethics is separated from the task of societal impact. Both of these tasks are led by PRIO, and it is clear that there are indeed overlaps between the two. E.g. carrying out research in an unethical manner will for sure have societal impacts, and similarly, that an activity has societal impact, e.g. it fosters trust, can feed back and influence the practical implementation of research ethics guidelines. Nonetheless, in DRIVER+, these two tasks are separated, also because of the outputs of the tasks. While the research ethics task (producing guidelines, advising the partners, monitoring ethics approvals etc.) is applied to DRIVER+ and is a continuous effort in the project, the societal impact task will ultimately produce a consolidated approach to doing societal impact assessments in the crisis management context, and will live on as one outcome of DRIVER+ (while not explicitly linked to its concrete activities).

⁵ Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC.

1. Questionnaires filled out by all the SP-leaders required giving input as per the new DRIVER+ DoW.⁶ The returned questionnaires cover all SPs, and the SP-leaders were given the option of either answering the questionnaire on behalf of the WP's in the SP or to solicit input from the WP- leaders (PRIO recommended the latter).
2. Minutes and reflections from the third DRIVER+ Ethical and Societal Advisory Board meeting, which held its third meeting of the project together with the regular AB meeting during a two day-meeting in Valabre, France in January 2018.
3. Issues of ethical concerns which has become apparent to PRIO as leader of WP913 Research Ethics and Societal Impact Assessments and the consequential tasks and responsibilities within the WP.
4. The deliverable finally also repeats and refines some core points from previous deliverables, since new partners have entered the project since the last report was published. As mentioned in the introduction, the submitted report will be shared with the consortium, to remind all partners of their obligations and of the role of PRIO as leader of WP913 Research Ethics & Societal Impact Assessments.

The process described above represents a change from previous deliverables, which was implemented to reduce the administrative burden and streamline the process. Instead of collecting reports on ethical issues from each partner organization (a very time-consuming task for both parties, especially given the resources allocated to this task), PRIO chose to be more pragmatic, and to rather collect feedback about ethical challenges/ issues from the SP- leaders. In this way the feedback is also more easily tailored to the different core parts of DRIVER+, such as Trial-specific issues which can be more easily tackled in one go. Since the nature of the project has changed, and the activities are becoming more realistic, the previous routine for collecting feedback from everyone was deemed less relevant, since it seemed more valuable to rather focus on overarching issues. However, PRIO still remains available for advice and guidance for all the partners that have particular challenges or questions.

1.3 Structure of the Deliverable

The deliverable is structured in 6 sections. Section 2 will describe and discuss the implementation of the GDPR on DRIVER+ activities, in particular the Trials. Section 3 is about research ethics in the context of the DRIVER+ Trials. Section 4 describes and summarizes highlights from the third meeting of the DRIVER+ Ethical and Societal Advisory Board meeting in January 2018. Section 5 shortly describes the current status of the revision of the Societal Impact Assessment (SIA) framework, and the SIA trainings, while Section 6 finally includes some concluding remarks. In annex to the deliverable, the template for the ethical monitoring questionnaires, which was sent to all SP leaders, can be found. The key issues described in the questionnaires are reflected in this report, and the collected questionnaires can be retrieved from PRIO upon request, e.g. by the PO or the ESAB. The two versions of informed consent forms which were developed for Trial 1 are available on the CoW under "Ethics tiles". These will be revised accordingly for the next use.

⁶The key issues described in the questionnaires are reflected in this report, and the collected questionnaires can be retrieved from PRIO upon request, e.g. by the PO or the ESAB. The fact that not every detail on information from the questionnaires are described in this report does not mean that PRIO is not following up on the identified issues.

1.4 The scope and limitations of the DRIVER+ Ethical Monitoring Report 3

This third report repeats and reiterates some information from previous ethics deliverables since there are new partners in the consortium, and since collecting updated information about research ethics in this report, makes it easier to distribute this information to the consortium. As with the second version of this report, the purpose is to identify and address *key* ethical issues, and this includes making a distinction between smaller issues of anticipated less importance that are (or have been) easily solved between PRIO and the relevant partner through T913.1 *Procedural Ethics*, and the more overarching, general and fundamental issues which are or will most likely be of relevance to more or less the DRIVER+ consortium as a whole, or that poses more significant risks to the project should they not be addressed. The deliverable does not aim at summarizing *all* ethical issues since the last report was submitted in April 2016, but rather to focus on the state of the project at this point, and to tailor the relevant information that PRIO will be providing for the next reporting period thereafter. However, in addition to all the submitted deliverables from WP913 *Research Ethics & Societal Impact Assessments* and the adhering WP's that existed in the previous project, PRIO has made summaries of all the key issues, including a list of recommendations. These are available under "Ethics tiles" on the CoW. The next section concerns the fundamental research ethics issues relating to data protection and privacy, a topic that many of the DRIVER+ consortium members come into contact with, directly or indirectly, especially given the current implementation of the GDPR across Europe.

2. Implications of the GDPR on DRIVER+ and WP913

This section will sum up the key implications of the GDPR in general, and on DRIVER+ activities in particular. Parts of this section are derived from Section 5 of D922.21 *Trial Guidance Methodology and Guidance Tool Specifications (version 1)* (7), where some general guidance and suggestions for implementation of research ethics requirements into the Trial Guidance Methodology was already provided. However, the aim of this section is to go more into detail, and to make an attempt to specify the requirements, especially as they are relevant for the upcoming Trials. The insights and challenges reflected in this section are also based on feedback from the DRIVER+ Ethical and Societal Advisory Board, as well as the main author's participation in a GDPR reference group at her research institute (PRIO). In addition, several guidelines, strategies and resources published by an array of national (e.g. NSD - Norwegian Centre for Research Data and Datatilsynet- Norwegian Data Protection Authority) and international (e.g. the GDPR Portal at www.eugdpr.org) institutions have been consulted for this section, as well as for the future work on making sure that DRIVER+ is adhering to the new requirements. It should also be noted that this work does not in any way end with this deliverable, but it is a work in progress which is reflected throughout the different tasks of WP913 *Research Ethics and Societal Impact Assessments*, although most notably in T913.1 *Procedural Ethics*.

The decision to adopt and implement the GDPR has been received with different levels of enthusiasm in various professional environments across Europe. Much of the criticism of the GDPR has described the new regulation as being an unnecessary burden, especially on SMEs and smaller organizations. At the same time, supporters of the legislation argue that the GDPR is actually more of an “evolution” than a “revolution”, implicitly referring to its gradual development and the fact that the GDPR is building on foundations already in place for the last 20 years⁷. Many of the pre-existing fundamental requirements remain the same in the new regulation, and adhering to these requirements should, according to e.g. Steve Wood, Deputy Commissioner at the Information Commissioners Office in the UK, be what you are already doing in your organization. E.g. practising data minimization (collecting only the data you need) could already be part of an organizations record-keeping practise, and similarly, being accountable for the data being collected by an organization is most likely already part of that company's trustful relationship with the clients or costumers. In fact, trust is a key concept in the GDPR. By expressing and having a clear data handling culture, organisations and businesses can potentially build valuable trustful relations with the public. This will not only be of value with regards to the sustainability of the organization, but it can also protect against reputational damage and financial loss, e.g. due to the high fines for non-compliance inherent in the GDPR⁸. In fact, it can even be seen as a competitive advantage for organisations that are careful with compliance, in the sense that research shows that individuals are more willing to provide their data (for different uses) if they feel like they can trust the organization to handle the data fairly, securely and responsibly.

One of the key changes in the GDPR is the strengthening of individual rights, such as the so-called subject access rights. This particular right means that any person whose data has been collected will have the right to access the data that has been collected about them, rectify wrong data, and ask for irrelevant or false data to be deleted. Thus, it is likely that the number of subject access requests will increase, and this could potentially be seen as an administrative burden. However, the individual access right existed also in the old Data Protection Act, so also here; the GDPR is a continuation rather than a leap into the unknown. In order

⁷ See e.g.: <https://flowz.co.uk/myth-5-gdpr-is-an-unnecessary-burden-on-organisations/>.

⁸ <https://flowz.co.uk/myth-5-gdpr-is-an-unnecessary-burden-on-organisations/>.

to give a short introduction to what the aim of the new regulation entails, a few facts about the regulation itself is relevant. The general data protection regulation (GDPR⁹) is part of the EU data protection reform package, along with the data protection directive for police and criminal justice authorities. It allows European Union (EU) citizens to better control their personal data. It also modernises and unifies rules allowing businesses to reduce red tape and to benefit from greater consumer trust. Those organizations handling sensitive or particularly intrusive data (which is presently not the case in DRIVER+) should be most concerned with the new requirements. The GDPR also strengthens existing individual rights by ensuring that companies and organisations will have to inform individuals promptly of serious data breaches. They will also have to notify the relevant data protection supervisory authority.

In order to assist organizations in ensuring compliance, several guidelines and step by step instructions by a wide array of offerors are available online. By browsing many of these guidelines, a few common traits can be identified. The first step is almost always to carry out a data mapping. In simple terms, this means to get an overview of what kind of data your organization has, where it is stored, and whom it is shared with. The reason for this being the first step is that it is only by creating awareness (of the data) that data subjects' rights (such as the access right) can be followed. By creating this overview, organizations are better equipped to be accountable for their use of personal data, and thus to create or maintain trustful relations. The second step is often to create and implement a plan for data retention. Data minimization was already a key principle in data protection law, and most organizations should already be collecting only the data that they will need. This becomes even more important with the GDPR, also seen in context with the rapid development and the possibilities for Big Data collection. As for the third step, and partly based on step 1 and 2, the organization should update the data protection statements and policies, to inform data subjects about their handling of personal data.

With the GDPR, since the individual rights have been strengthened, the list of information that should be disclosed to the public has also grown. The key issue with this is to avoid that the data subject, whether (s)he is a consumer, employee, or a member, can file a valid complaint with regards to the wrong use of personal data. Furthermore, this should also be done for supplier agreements, for external service providers or outsourcing suppliers. As a fourth step, the conduction of risk assessments might be appropriate. In particular, data protection impact assessments (DPIAs) might be necessary. However, this is not required of all organisations and businesses. The new regulation acknowledges that there are some important distinctions: "As an economy-wide, cross-sector regulatory instrument, the GDPR recognise the difference between a data breach involving only individuals' names and job titles and one leaking patients' genetic records."

For high-risk activities, the GDPR requires companies to perform a DPIA. This means going through a structured process of identifying, documenting and sometimes reporting the likelihood and severity of privacy risks for individuals as well as measures of mitigation that the company intends to take¹⁰. Following the same general logic, the fifth step can be identified as the need to appoint a dedicated data protection officer (DPO), and where necessary, a European representative. The requirements for appointing a DPO are quite broad, and should be assessed in each individual case. The International Association of Privacy Professionals (IAPP) conservatively estimates that 28,000 DPOs will need to be appointed across the private sector in the EU before May 2018¹¹. The GDPR states that DPOs should have

⁹ Regulation (EU) 2016/679 — protection of natural persons with regard to the processing of personal data and the free movement of such data. Available at: http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG.

¹⁰ A description of these steps can be found at: <https://flowz.co.uk/how-to-be-prepared-for-gdpr/>.

¹¹ Available at: <https://www.lexology.com/library/detail.aspx?g=e51b0930-497f-439c-a870-95019cbb1f9a>.

“expert knowledge of data protection law and practices” (quoted from Article 37(5), and that they should be able to practically fulfil the tasks. The sixth step is about preparing the technological side of the organization for the GDPR. In DRIVER+ terms this would be what Guidance Tool is to the Trial Guidance Methodology. The preparation of the technologies should be done in order to prepare for individuals enforcing their (new) rights, such as the right to be forgotten as well as rights of individual access, rectification, revocation of consent, portability etc. Finally, full compliance with the GDPR was still a work in progress for many organizations by the 27/06/2018. There is reason to believe that the large fines and the strict sanctions for non-compliance will be handled with some flexibility in the beginning, but nonetheless it is crucial for organizations to demonstrate that they take the GDPR seriously, and that they have initiated systematic and serious work to implement the GDPR requirements.

Based on what has been described above, for the DRIVER+ Trials, the changes that come with this new regulation will refer to *citizens’* rights. In the GDPR, the rights of the data subject are detailed in Chapter III. This chapter of the regulation consists of several sections, each with a name that indicates the key issues when it comes to data subject rights: 1. Transparency and modalities, 2. Information and access to personal data, 3. Rectification and erasure, 4. Right to object and automated individual decision-making, 5. Restrictions. While the new rules for *businesses* are also highly relevant for DRIVER+, the implementation and enforcement of these lie with the individual company/business/organization taking part in the project¹².

This means that the ethical component in DRIVER+ (e.g. as it is currently developed as part of the Trial Guidance Methodology) will not be aimed at assisting businesses in adapting to the GDPR, but it will first and foremost take into account the rights of the data subjects who are potentially participating in the Trial activities.

In sum, the GDPR has been developed to strengthen existing rights, to provide for some new rights and to give citizens more control over their personal data. The GDPR formulates a handful of privacy principles, which structure the requirements and recommendations below¹³. These principles relate to the processing of personal data, which is covered in Article 5 of the regulation. In order to protect the privacy of participants in the Trials, but also for every other activity in DRIVER+, personal data needs to be processed in accordance with data protection rights¹⁴. The definition of “personal data” is derived directly from the legislation under Article 4: ‘personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. It is important to note, however, that by suggesting and enforcing rather strict data protection guidelines for DRIVER+ since the very beginning of the project, the assumption is that by complying to the Data Protection Act and at times even adhering to stricter rules than necessary (e.g. for informed consent), the partner organizations in DRIVER+ should already be well on their way to being ready for GDPR, at least in the context of the project. Ensuring that the different legal entities that make up the project consortium comply with the new legislation is outside

¹² A summary of the key rules for businesses can be found here: http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG.

¹³ A similar list describing the six key principles of GDPR has also been made by MThree Consulting. This list can be found here: <https://www.mthreeconsulting.com/blog/2017/04/the-6-privacy-principles-of-gdpr>.

¹⁴ At the time of which this deliverable is submitted, there is no reason to believe that so-called “special categories of personal data” will be processed within the scope of DRIVER+. However, if this will be the case, special requirements, as detailed in Article 9 of the regulation, applies.

the scope of PRIO's responsibility in the project, although PRIO offers guidance and advice on this matter in the cases where it is needed. The questionnaires distributed for writing this deliverable also asked the question of how the organizations have taken the new requirements into account. In the Ethical Monitoring Questionnaire, one WP reported that they are keeping a contact list with names and contact details for people who have or have had contact with DRIVER/DRIVER+. These people are contacted with relevant information such as information about open calls for applications and invitations to participate in the Trials. With the GDPR the responsible WP are aware of the new requirements as described above, and have sent out an email to the full list, asking the registered people to confirm that they still want to be on the list. While the true operational readiness depends on whether or not the various DRIVER+ partner organizations have an effective data governance programme in place, the general principles of fairness, transparency, data minimization, individual rights, etc. have been raised by PRIO since the very first deliverable was submitted already in M2 of the project. And it is these principles that the GDPR is built on.

2.1 GDPR requirements relevant for the DRIVER+ Trials

While most of the requirements listed above mainly refer to the preparation phase of a Trial, some are also relevant for the execution and the evaluation phases. In the list below, the different requirements are tied to which phase they are relevant for. This was done in order to link them to the different phases of the Trial Guidance Methodology (TGM). To reflect the new data subject rights described in the GDPR, the following legal requirements should be followed¹⁵. In the list below, key requirements from the legislation are introduced. After the introduction, a bullet point list follows. This bullet point list contains requirements that are structured according to the different phases of the TGM, i.e. preparation, execution, and evaluation.

Lawfulness, fairness and transparency:

The GDPR clearly states that processing of data shall be lawful only if and to the extent that at least one of several conditions applies. These conditions are e.g. the data subject has given consent to the processing of his or her personal data for one or more specific purposes. Lawfulness of processing is further described in article 6 GDPR.

- Preparation: Tell the data subject (the person which personal data is collected from) the data controller's identity and contact information, what kind of data will be collected and processed, and make sure that the data actually collected matches this description. Provide information about the purpose of the research, who will receive access to the data and how long the material will be stored. An updated notice should be given when a controller intends to process data for a further purpose.
- Preparation: Make the conduct of observation or recording of people very clear. Give anyone potentially affected by it the possibility to refuse from being observed or recorded.
- Evaluation: Facilitate de-briefing for research activity participants when relevant (such as for external participants in Trials with a large field component with extensive scenarios). PRIO can help determining if this is necessary in particular cases.
- Preparation: Always inform all participants and potential bystanders thoroughly and well ahead of the conducted research. For participants in the Trials see first bullet point. In the event that

¹⁵ Several deliverables in WP913 will deal with the GDPR and the overall task of research ethics, but this list provides an overview of current general key recommendations relevant for the DRIVER+ Trials. Specific considerations for each Trial, as they evolve, will be discussed between PRIO and the Trial owner/ Trial committee. It should also be noted that this deliverable does not provide a full account of the complete legislation, but highlight only what are deemed most relevant for the project as it looks at the present stage.

bystanders could be affected by the activity, by e.g. being exposed to a Trial scenario with a field component, as much information as possible should be given to them in advance. This can e.g. be done by putting up information posters in the vicinity of the Trial area. This would be considered good practice, even though the bystanders are not “data subjects”¹⁶.

- Preparation: If needed, consult local data protection authorities to make sure that rules and regulations ensuring data protection rights are followed. Registration with national authorities must be made where required. With GDPR, there is no longer a requirement to notify. However, other responsibilities apply, which may affect the rights of the participants, such as the duty to carry out data protection impact assessment and conduct prior consultations (descriptions of when this is relevant can be found in article 35 and 36 of GDPR).

Collection, processing and purpose limitations:

The GDPR states that personal data can only be obtained for “specified, explicit and legitimate purposes” [GDPR article 5, clause 1(b)]. GDPR also states that data subjects should be able to “consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.” This demonstrates that the Regulation permits more relaxed specificity in the notice provided for research processing. Article 17 supplies each data subject with the right to have her personal data erased when she withdraws consent or objects to the processing, as well as when the data are no longer needed for the purpose for which they were first collected.

- Preparation: Although there is no longer a requirement to obtain informed consent in the GDPR, PRIO would still recommend to inform participants in advance of the activity about what will be required/ expected from them, and how the result of their contribution will be used. If the decision by a task leader is to follow the “old” practice, it is still important that the consent is given actively¹⁷.
- Preparation/execution/evaluation: Ensure that data is not being used for any other purpose than what GDPR article 5, clause 1[b] states.
- Evaluation: Do not re-use data without written agreement of the owner.
- Preparation/execution: The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her (GDPR article 22). If such processing is necessary in DRIVER+ (e.g. for the ‘potentially automated’ performance measurement and logging using technical infrastructure in SP92), the decision must be based on the data subject’s explicit consent (according to GDPR article 22, clause 2(c)).

Data minimisation:

The GDPR states that data collected on a subject should be “adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed” [GDPR article 5, clause 1(c)].

- Preparation/execution: Practice data minimization, i.e. avoid collecting unnecessary data.
- Evaluation: If personal data is contained in the description of Trial results which is stored in the PoS, this should be justified.

¹⁶ However, this is dependent on the situation. If there is video surveillance or tracking of bystanders by the solution providers, then they may become data subjects.

¹⁷ The conditions for a valid consent is formulated in article 4, 7 and 8. There is e.g. a requirement of explicit consent. The requirement may be fulfilled by clicking for consent.

Accuracy:

The GDPR states data must be “accurate and where necessary kept up to date” [GDPR art. 5, clause 1(d)].

- Execution/evaluation: Refrain from processing data that is not up-to-date.
- Execution/evaluation: Be aware that under the GDPR any person located in the European Union (anyone residing in the EU, not just EU citizens) can request their personal information be removed from a corporate database, or know the reason why it can't.

Storage limitations/Integrity and confidentiality:

The GDPR states that personal data should be “kept in a form which permits identification of data subjects for no longer than necessary” [GDPR article 5, clause 1(e)]. The GDPR also states that those processing data should do that “in a manner [ensuring] appropriate security of the personal data including protection against unlawful processing or accidental loss, destruction or damage” [GDPR article 5, clause 1(f)].

- Preparation/execution/evaluation: Collected data which is no longer required should be deleted. In case of a data breach, this will lessen the amount of affected individuals.
- Preparation/execution/evaluation: Ensure that personal data collected is stored in a secure way, e.g. by using the ISO/IEC 27000 family of standards¹⁸ or the kind of guidance provided by National Cyber Security Center in the UK¹⁹.
- Preparation/execution/evaluation: Anonymize and encrypt personal data as a general rule.
- Preparation/execution/evaluation: Use technology for data recording only if necessary, and justify.

In Section 3 of the regulation, “Data protection impact assessments and prior consultation” is detailed. Article 35 states that “Where a type of processing in particular using new technologies, and taking into account the nature, scope, context and purposes of the processing, is likely to result in a high risk to the rights and freedoms of natural persons, the controller shall, prior to the processing, carry out an assessment of the impact of the envisaged processing operations on the protection of personal data. A single assessment may address a set of similar processing operations that present similar high risks”. The controller shall seek the advice of the data protection officer, where designated, when carrying out a data protection impact assessment. A data protection impact assessment referred to above (in paragraph 1, Article 35) shall in particular be required in the cases listed in the following quote:

- (a) A systematic and extensive evaluation of personal aspects relating to natural persons which is based on automated processing, including profiling, and on which decisions are based that produce legal effects concerning the natural person or similarly significantly affect the natural person.
- (b) Processing on a large scale of special categories of data referred to in Article 9(1), or of personal data relating to criminal convictions and offences referred to in Article 10.
- (c) A systematic monitoring of a publicly accessible area on a large scale.

In the context of DRIVER+, in the event that some of the Trials fulfil one of these criteria (e.g. includes “a systematic supervision of a public area”), the requirement to carry out a data protection impact assessment could be relevant. In such cases, section 3 GDPR will be consulted for more information about this issue.

¹⁸The standards can be found at: <https://www.iso.org/isoiec-27001-information-security.html>.

¹⁹This contains expert, trusted, and independent guidance for UK industry, government departments, the critical national infrastructure and private SMEs. All the guidance is advisory in nature and is underpinned by NCSC's insights into cyber threats. Available at: <https://www.ncsc.gov.uk/guidance#atglance>.

3. Research ethics and data protection in the context of the DRIVER+ Trials

This section addresses ethical issues arising in the context of the DRIVER+ Trials and engages with the way they have been conceptualized, prepared, rehearsed, and executed. It starts by providing a description of the (planned) integration of both the societal impact assessments framework and research ethics into the Trial Guidance Methodology (TGM). It then follows with a more general section about the execution of the Trials and additional reflections on the approach adopted in DRIVER+. Highlighted in the Ethical Monitoring Questionnaires by the relevant partners, it is crucial that WP913 follows the further development of the TGM closely, so that D922.41 *Trial Guidance Methodology and guidance tool specifications- version 2*, and D922.42 *Handbook for systematic designing of Trials* always reflects research ethics considerations, which are also based on lessons learned from Trials.

Trial 1 took place in Warsaw in 21-25/05/2018. Part of the preparatory work towards Trial 1 has happened during Workshop 0, a general rehearsal exercise that took place in Warsaw in late February and early March 2018. This workshop will be analysed below. Before that, PRIO submitted D913.11 *Ethical Approval 3* in M44. This deliverable describes the third round of ethical and data protection approvals and notifications required by the DRIVER+ partners for activities between M41 (September 2017) to M47 (March 2018). The deliverable was the third of its kind, and an additional deliverable is scheduled to be submitted at a later stage. The aim of this line of deliverables is to uphold a continuous overview of the status of ethical approvals throughout the project. The sequencing of the deliverables allows a comparative analysis of research ethics issues at different stages of DRIVER+ and provides a concrete identification of the aspects that require new procedures. After the restructuring of the project, the most important approvals needed for the various DRIVER+ tasks remain data protection approvals that are issued by the local data protection agencies of those partners who lead the respective tasks. These constitute most, if not all approvals foreseen within DRIVER+, and were already implemented in Trial 1. Integration of Societal Impact Assessments and Research Ethics into the Trial Guidance Methodology.

The integration of SIA into the TGM follows a two-stage process. In the first stage, the objective is to develop a framework for conducting the SIA; in the second, the focus is on incorporating that framework into the broader TGM. The difficulty of doing SIAs in a project that does not develop technologies resulted in the approach described below and in D840.11 *Societal Impact Assessment Framework version 1* (8). These issues are work in progress but have been addressed in more detail in D922.21 *Trial Guidance Methodology and Guidance Tool Specifications- version 1*. There, it was described that making a societal impact assessment, following the current version of the SIA framework that exists in DRIVER+ would typically include the following elements:

1. A short description of the CM function/ assessment object, what it refers to, mainly with regard to its relevance and use within DRIVER+, but also to CM in general. This introduction also includes an illustration, which is practically an entryway into the assessment. Already by providing this description, critical thinking about the respective function/ assessment object could be incited.
2. The actual assessment is the core of the procedure, which is basically a systematic analytical exercise structured by the different criteria.
3. A concrete recommendation to provide the user with actionable advice. It includes concrete tips and guidance on how to choose solutions in a way that negative impacts are avoided, and opportunities seized. A set of example assessments will be delivered to go with the final version of the framework so that premade assessments can be used for reference, inspiration or guidance for Trial owners in how to conduct an assessment themselves.

In sum, the framework allows for assessment of various functions that a CM solution can have by using a coherent set of impact criteria. When considering a solution for a Trial, the various functions that the relevant solutions perform can be assessed by applying the criteria. This can include a scenario-thinking

exercise (describing likely future scenarios of societal impact), research on concrete examples of impacts that happened in the past, background literature (e.g. on underlying logics and assumptions), or the assessment can draw on personal experience from the field. The assessment should be concise and critical, and at the same time draw attention to the effects that the planned CM function may have on society, but also result in recommendations for concretely how to avoid (unintended) negative impact and foster positive impact.

While the SIA framework exists in a first version, this has to be revised and updated to be more relevant for the project. One way this revision will happen is by “trailing” the method (as well as training project partners in thinking about societal impact issues) on the consortium, and using their feedback to redesign the framework. The issue of SIA, in particular the training sessions on how to conduct SIA, was discussed further between PRIO and EOS in a meeting at PRIO on 14/06/2018. The main issues addressed in the meeting were the following:

- Alignment of the training session’s content with broader societal impact considerations.
- Structure of the sessions, adapted to the different settings in which they will take place.
- The reinforcement the centrality of SIA in the project.
- Long-term thinking and the issue of the WP913 DRIVER+ legacy.

The meeting advanced the preparation of the training sessions significantly and enabled a greater awareness of the challenges and opportunities that surround these sessions. PRIO and EOS identified the centrality of the SIA Framework in the whole TGM as a potential challenge. This issue is related to the fact that the SIA Framework will be refined throughout the project and therefore its incorporation in the training sessions poses some challenges that require new solutions that was discussed extensively.

In the context of the Ethical Monitoring Questionnaire, DRIVER+ SP-leaders provided input on research ethics-related issues. It has been highlighted that there are some cross-SPs issues that should be tackled. Besides the Observer Support Tool, the way in which data will be handled in the Guidance Tool is relevant, for instance. Requirements for the development of the GT are provided in SP92 but the tool itself is developed in SP93. Therefore, cross-SP dialogue on research ethics-related issues should be facilitated on a regular basis. It is important that PRIO follows closely the development of the TGM so that D922.41 *Trial guidance methodology and guidance tool specifications- version 2* and D922.42 *Handbook for systematic designing of trials* always reflects research ethics considerations also based on lessons learned from Trials. Finally, it has been suggested that a new section is created in the Project Handbook focusing specifically on ethical issues in the context of the Trials.

3.1 Issues and challenges when conducting Trials

The overall objective of DRIVER+ Trials is to investigate to which extent potential solutions solve gaps and/or meet needs that have been identified by practitioners in the domain of CM in Europe. It is important for the success of DRIVER+ that this investigation is conducted in a way that is societally acceptable, that research ethics rules and procedures are followed, and that potential negative impacts are mitigated and minimized, or eradicated if possible. Trials are a key component in DRIVER+, and it is crucial for the success of the project that the Trials are prepared, executed and evaluated in a well-thought-of way. Although GDPR no longer requires informed consent (see Section 2), it is still recommended that all partners in the Trials are made aware of the activities and the extent of the activities they are taking part in. A template for an exhaustive information sheet and informed consent sheet to be used for the DRIVER+ Trials has been prepared by PRIO, and it should be tailored by the Trial owner in the preparation phase of the Trial, and the information sheet and informed consent sheet should be distributed to all external participants two weeks before they are involved in the research activity. In case only a very basic form is required (e.g. because information has already been given in a Non- disclosure agreement (NDA) or in the Confirmation of Commitment), a simpler version of an informed consent form has been prepared. Based on the information derived from the Ethical Monitoring Questionnaire, most respondents’ report to either

having used the template, being aware that it is available or that they are planning to use it for specific activities in the future (when relevant). Some partners state that the template is actively used for every activity involving externals, other state that they revise it slightly to fit their needs, and others report that they have concrete future events in mind when this will be necessary and relevant to use. The updated templates will be published on the CoW.

For Trial 1, a less extensive version of this form was deemed most relevant, and it was distributed to all external participants (following the distribution also of the Confirmation of Commitment and the NDA) in order to secure their privacy and data protection rights. However, the forms will be revisited after each Trial, to ensure that they meet the needs of the Trial owners; hence they will also play a role in the evaluation phase of the Trials.

3.1.1 “Workshop 0” and the preparation of the Trials

In the process leading up to the preparation of the Trials, an important milestone was “Workshop 0” that took place in Warsaw between 26/02/2018 and 02/03/2018. The “Workshop 0” provided a number of different settings in which consortium internal solution providers presented and demonstrated the solutions that they were considering including in the Trials. This exercise raised awareness to the Trial Committees on what kinds of solutions are available within the consortium. Moreover, a “mini-Trial” was conducted to explain and demonstrate in a concrete way both the Trial Guidance Methodology (TGM) and the Test-bed. This was a crucial step in the process of developing the TGM. It further clarified for the Trial Committees what is being expected from them, and provided the TGM design team with helpful feedback. Additionally, the Trial Committees had several working sessions on preparing their respective Trials, while the Trial 1 Committee organized dedicated sessions (presentations, demonstrations, Q&A) with both internal and external solution providers who were positively assessed by the Solution Review Group following the Call for Application. Directly after WSO, 3 external and 1 internal solution providers were selected to participate in Trial 1.

Out of W0 a few important issues arose. Even though the W0 was crucial in identifying potential caveats in the process, it also made the consortium aware of the limited timing until DR1 and Trial 1. At the same time, it revealed that not all partners were fully aware of the different components of DRIVER+. The fact that fundamental knowledge was still missing poses challenges for PRIO and other participants to ensure the centrality of the SIA in the whole structure of the project. Finally, it emerged as very important to have plain language and easy English-language formulations in the documents to be provided to external participants in the Trials, namely solution providers, observers and validators. Grains in the communication affect the efficiency of the message and may have relevant implications in terms of issue awareness and informed consent. PRIO remains available for reviewing such documents.

3.1.2 Ethical issues and the realization of Trials

In DRIVER+, innovation is a key component. The project aims at developing an innovative way of evaluating CM solutions in Europe by providing a TGM, by enhancing a structured way of conducting SIA, by offering a Test-bed where different solutions can be tested, and by providing a Portfolio of Solutions where different CM solutions can be found. The innovation dimension, therefore, does not stem from new technology, but rather from an innovative methodology to evaluate, test, and display CM solutions. Even though DRIVER+ does not aim at developing new technology, its focus on innovation nevertheless relates to several debates that take place within Responsible Research and Innovation (RRI), a key theme in the governance of science and technology in 21st century. For the European Commission, RRI is “an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation”. This means that societal impact aspects should be central to all the research, technology and innovation produced in Europe. Within this logic, DRIVER+ is exempted from some of the pathologies of innovation that are often considered in

the discussions surrounding RRI: unpredictability and uncontrollability of large socio-technical systems, institutional ignorance of early warnings, the altered nature of human action, and the tendency towards hype, among others. Yet, this implies that the aspects of societal impact gain increased prominence in the RRI considerations surrounding the planning, execution and evaluation of the Trials and other activities in DRIVER+, in particular the TGM.

In this regard, an important aspect to consider is timing. The adequate implementation of the DRIVER+ procedures in the run-up to the Trials, including familiarization with the TGM, requires some preparation ahead of the Trials, and therefore sufficient time between the solution selection, Dry Runs and the Trials should be guaranteed. The external solution providers need to be informed in advance about the Test-bed and need time to become acquainted with the TGM. Short timing before the Trials impacts negatively on the preparation and prevents the observance of best practices.

At the same time, it is important to ensure that all consortium partners share the understanding of key concepts of the project, such as the TGM and the Test-bed. In other words, it is crucial that the project's key components and terminology are understood in the same way by all the participants in the Trials. As the project unfolds this issue will become less relevant, but at the current stage it should be considered central.

4. The DRIVER+ Ethical and Societal Advisory Board

The following section will briefly describe the third meeting of the DRIVER+ Ethical and Advisory Board, which was held in Valabre/ Aix-en Provence in 15-16/01/2018. A more detailed discussion about the ESAB, the discussions and the next few meetings will be provided in the upcoming D913.21 *Minutes of ESAB meeting 1 and 2*, which is due in M52. However, some reflections relevant for this report are given below.

According to the new project structure, the ESAB is formally placed in WP913 *Research Ethics and Societal Impact assessment*, in Task 913.2: *Ethical and Societal Advisory Board* (lasting from M41 to M70). The task, as well as the WP, is still led by PRIO. Beyond PRIO and the Board members, there are no partners to T913.2 *Ethical and Societal Advisory Board*. The main outputs of the task are the minutes of ESAB meetings, delivered as D913.21 *Minutes of ESAB meeting 1 & 2* and D913.22 *Minutes of ESAB meeting 3 & 4*. The Ethical and Societal Advisory Board (ESAB) was established at the very beginning of the project, and consists of three experts on research ethics and societal impact issues.²⁰ The composition of the ESAB has not changed as a consequence of the vast project restructuring processes and outcomes, and it should be noted that PRIO as the coordinator of the Board are grateful for the valuable dedication and backing of the Board members- both as a collective and as individual supporters.

The group has had three meetings so far in the project, but have kept in touch throughout the project duration. The ESAB has been frequently consulted on particular relevant issues. During the face-to-face meetings, PRIO and the ESAB discuss research ethics issues and questions that are relevant to the project and have been mentioned by partners in the ethical monitoring reports such as this one (delivered as part of T913.1 *Procedural Ethics*). In addition to research ethics, the Board is also consulted on societal impact issues, and the next meeting between PRIO and the ESAB will focus on the revision of the Societal Impact Assessment Framework, which will be delivered as part of T913.3 *Societal Impact Assessment Framework*, by the end of the project. In all cases, PRIO is the link between the ESAB and the rest of the project. The Ethical Monitoring Reports (where input is gathered directly from the Subprojects) are the key vantage point for the meetings between PRIO and the ESAB.

The ambition and aim of the meeting in Valabre in January 2018 were seen in the context of the challenging history of the project, and was the first formal meeting of both the DRIVER+ Advisory Board (AB) and Ethical and Societal Advisory Board (ESAB) since the DRIVER+ project officially restarted on 01/09/ 2017. After all the changes and restructuring, it was deemed necessary to provide both the AB and the ESAB with a coherent update on the project. The original idea (as discussed by the PRIO project leader and the DRIVER+ Project Director) was to join these two meetings on the first introductory day, and then to have specific meetings with each Board on the second day, for more in-depth discussions on the relevant issues. As will be later described in more detail, it was decided to arrange joint meetings for both Boards on both days, but a brief description of the meeting on the first day will first be provided.

During the meeting on the first day, the key ambition was to provide the two Boards with a thorough introduction to the DRIVER+ project. As mentioned in Section 3.1.2, having a shared understanding of the project is crucial for the project partners and the individual projects participants, researchers, etc., but it is of course also crucial for the DRIVER+ Advisory Board (AB) and Ethical and Societal Advisory Board (ESAB). Thus, the meeting on the first day included several presentations which highlighted all the changes that were implemented following the EC review, as well as an explanation of why the relaunched project is

²⁰ The members of the ESAB are Helene Ingierd (NENT), Vasiliki Petousi (University of Crete), and Katarina Hadjimateo (University of Warwick).

organized the way it is. Also during the joint meeting on the first day, all the different Sub Projects were presented, and it was important to give plenty of opportunity for discussions and questions during these sessions.

On the meeting on 16/01/2018, the aim was to present the two main results which the project aims to deliver, namely the Test-bed (both the technical infrastructure and the TGM) and the Portfolio of Solutions. Some first initial results were shared, and feedback was provided from both boards. While the original idea was to have separate meetings with both boards during the second day, the members of the ESAB clearly expressed their interest in keeping the meetings joint also on the second day, due to the vast amount of information that was shared also about the general activities in the project (and not just related to societal impact and research ethics). As mentioned above, since the task of the ESAB is to give feedback and support to the project on two tasks that are really overarching for the project (both research ethics and societal impact cannot be seen as separate from the project), it was decided to have a joint meeting also on the second day. Although a PowerPoint presentation and working sessions covering a separate ESAB meeting had been prepared by the WP leader, the importance of, and the opportunity for, aligning the ESAB with the updated project during this joint meeting was deemed as more valuable at the point in time. The idea was to rather share the presentation and the writing material with the ESAB after the meeting, and to gather feedback, impressions and advice based on the presentation as well as the information received during the two joint meeting days. As agreed with the ESAB and with the DRIVER+ Project Director, this was done, and the next couple of sections are a summary of the feedback provided by the ESAB members to task leader PRIO.

4.1 Summary of feedback from the ESAB

In order to avoid overlaps and redundancies in the deliverables, the following sections complement, but do not replace, the formal minutes from the meeting. The feedback from the ESAB below has been anonymized, so that it is not linked to individual members.

Positive feedback with regards to the meeting: The meeting itself was described as both interesting and informing, although one member still admitted to have some open questions. Some of these questions are reflected in the draft minutes the ESAB received (put together by the AB chair) and in general referred to not so clear mapping of all activities in the project. A synopsis of the project (including an overview of roles and names) would be very useful for the ESAB.

Exchange of information: The Board members saw a “significant difference in the project” and highlighted some issues requiring further clarification (as described above). Since not all ESAB members had received the two-pager explaining the project in advance, it was described as “a bit more challenging to have a clear picture of the ethics issues involved”. The project management was thus requested to make sure that all ESAB/AB members receive all necessary information on time (especially before the meetings). One member of the ESAB also asked for an overview of all the names, roles and responsibilities in the project (something like an extended contact list).

Positive feedback with regards to the work in WP913: One Board member stated that WP913 has done “a very good job describing the issues and the challenges with ethics issues”, and at the same time that the “job is not easy (and I don’t see it getting any easier in the future)”. Another member expressed that “My overall impressions are positive. What you are doing makes a lot of sense. It’s clear and well thought through. That can’t have been easy to achieve in such a complex project. Well done.”

Informed consent: The issue of informed consent was also mentioned by the ESAB, since they were asked to give feedback on the PowerPoint presentation that the WP913 leader was originally meant to give during the meeting (but which was not done in the end due to reasons outlined above). One particular issue was about so-called “clicking for consent”, which has to do with e.g. a short version of an informed consent

from inside a mobile application, and whether or not that was sufficient as valid consent. With the GDPR this is less relevant, as described in Section 2, but according to one of the ESAB members the whole process could be seen as enhanced if collection of personal data was more explicitly referred during recruitment or if (whenever possible) printed signs or informative posters or similar were made visible during recruitment and during Trials with reference again to collection of personal data and availability of information on the app. In sum, a suggestion was to find ways to attract as much attention as possible to the personal data collection, the availability of information and maybe a sensitization that before participants 'click' they should read carefully. Another Board member suggested that it “might be good for PRIO to ask participants doing the clicking how it worked for them and what might be improved, so as to develop some knowledge that could feed into best practice”.

The Societal Impact Assessment Framework: Feedback from the Board stated that the SIA approach appears to be going the right direction. It is a bit complicated, but this stems from the nature of the project. A board member suggested to include (if and when available) more written text, more explanation and discussion. PRIO will take this into account when revising the framework.

Dissemination/sustainability: With regards to the long-term impact of DRIVER+, it was suggested in general by the AB that the long-term objective for crisis management could be the EU-certification of tools and testing methods. One ESAB member asked about the dissemination/sustainability plans for the SIA handbook and the training approach, and asked if it might be possible for these to feature in any certification, as discussed in the AB meeting, or if it might be possible to get commitment from a partner to use them in the long run. These issues will be discussed with T913.5 *Societal Impact Training modules and Training Sessions* leader EOS.

GDPR: One Board member committed to assist PRIO in writing the overview of the GDPR implications, as can be found both in D922.21 *Trial Guidance Methodology and Guidance Tool Specifications- version 1*, and in Section 2 of this deliverable. The comments and the issues raised are reflected in these two places, and will not be further detailed here. Again, the ESAB stated that having a project synopsis would be really helpful also for assessing the implications of GDPR (and ethical questions related to privacy data protection) on DRIVER+. Based on the information derived from the Ethical Monitoring Questionnaires, compliance with the GDPR is a recurring concern among partners, and there is an expressed wish to use the ESAB for assistance on this matter. While this can partly be done via the ESAB meeting and follow-up communication on specific issues, it should be noted that the ESAB does not hold legal expertise on this matter.

5. Revision of the SIA framework and plan for the SIA trainings

The following section will briefly describe the status of the other main task of WP913 *Research Ethics and Societal Impact Assessments*, in addition to the procedural research ethics which this report is mainly about, namely the societal impact assessments that are being done and will be done alongside the DRIVER+ Trials and other activities. While the focus of this report is not social impact assessments, the two aforementioned tasks are clearly linked. On the one side, not taking society, and the potential impacts on it into account when doing research, can be seen as both incorrect and immoral. On the other side, not taking research ethics requirements and common rules into account when doing research can have a huge impact on society. When we, nonetheless, chose to distinguish between the two when designing DRIVER+, it was to allow for a clearer separation between the more immediate and administrative issues of research ethics and the more long-term, conceptual and “incalculable” issues (societal impacts). To a large extent, this report focuses on the former, which is also clear given the title of the deliverable. However, the task leader would like to take this occasion to also formalize in writing the current status of the societal impact assessments tasks. One reason for this is that since the first version of the Societal Impact Assessment (SIA) Framework was delivered, almost the entire duration of the project will have passed before the second and final version of the framework is due for submission. This final version, and the plans for it, is closer described in the actual deliverable (D840.11 *Societal Impact Assessment Framework version 1*), so only a short description of the surrounding process will be given in the following.

As mentioned above, on 14/06/2018, a meeting was held at PRIO premises in Oslo between task leader EOS and contributing partner PRIO. The aim of this meeting was to plan and prepare the SIA training sessions. One key lesson from the meeting is the importance of emphasizing that the ultimate aim for the trainings is not only to train project partners in using the SIA framework, but it is also about refining and revising the framework and the methodology itself, in order for WP913 *Research Ethics and Societal Impact Assessments* to be able to deliver a complete approach to “Societal Impact Assessments for the Crisis Management sector” at the end of the project. In other words, WP913 *Research Ethics and Societal Impact Assessments* will also “trial” the SIA trainings for the consortium and the systematic feedback that will come out of the trainings will be used to revise this approach in general, and the SIA framework specifically. Towards the end of the project, a final set of training modules, based on the revised SIA framework and which will be useable beyond the project will be delivered. The general idea is that the consortium partners will receive this training in order to become more aware of potential societal impact of the crisis management tools and solutions they are working with, and that at the same time, the concrete method will be improved and refined through the trainings, since feedback gathered by the trainers will be used to revise the method (both the actual SIA framework and the training approach) based on trainees with real-life crisis management experiences and reflections that will help improve the method. The trainings will be structured in two parts; one introductory session, as well as more specific and applied group work sessions. The first training will take place during the upcoming General Assembly meeting in September 2018. Here, the introductory session will be given to the whole General Assembly, followed by specific sessions that partners can sign up for. For the later SIA training sessions, the idea is to arrange the trainings in collaboration with the organizers of the upcoming Trial Dry Runs. The trainings will include specific work cases that are relevant for the different Trial scenarios.

6. Final remarks

This deliverable is the third Ethical Monitoring Report, documenting and addressing key ethical issues in DRIVER+. The next Ethical Monitoring Report is due in M62, and will document and address ethical issues pertaining to the last phase of the project.

The deliverable has repeated and refined some core points from previous reports, both to clarify some particularly important points regarding research ethics and to update and specify some of the previously given recommendations and guidelines, especially taking into account the implementation of the GDPR in May 2018. This reiteration is also necessary due to a more operative and practical orientation in the DRIVER+ work, as well as due to the participation of new partners, constellations of partners, and the overall increased activity in the project.

For the next Ethical Monitoring Report, updates on ethical issues will be documented, and relevant issues will be discussed, but it is expected that the following reports will, to an even lesser degree, address fundamental issues relating to research ethics, and revolve more around the practicalities of collecting the approvals, and potential special ethical challenges in the project, relating in particular to the realization of the Trials and the Final Demo.

References

1. **Bergersen, Stine.** *D95.31 Ethical Monitoring Report*. s.l. : DRIVER project, 2015.
2. **DRIVER+ project.** *D130.42 Ethical Monitoring Report 2*. 2016.
3. —. *D913.11 Ethical Approval 3*. 2017.
4. **Marshall, G & Scott J (eds.).** *A Dictionary of Sociology*. Oxford : Pxford University Press, 1998.
5. **(NENT), the National Committee for Research Ethics in Science and Technology.** Guidelines. [Online] [Cited: April 28, 2018.] <https://www.etikkom.no/forskningsetiske-retningslinjer/Naturvitenskap-og-teknologi/>.
6. **DRIVER+ project.** *D91.3 Ethical Procedures, Risks and Safeguards*. 2016.
7. —. *D922.21- Trial guidance methodology and guidance tool specifications (version 1)*. 2018.
8. —. *D840.11 Societal Impact Assessment Framework- version 1*. 2017.

Annexes

Annex 1 – DRIVER+ Terminology

In order to have a common understanding within the DRIVER+ project and beyond and to ensure the use of a common language in all project deliverables and communications, a terminology is developed by making reference to main sources, such as ISO standards and UNISDR. This terminology is presented online as part of the Portfolio of Solutions and it will be continuously reviewed and updated²¹. The terminology is applied throughout the documents produced by DRIVER+. Each deliverable includes an annex as provided hereunder, which holds an extract from the comprehensive terminology containing the relevant DRIVER+ terms for this respective document.

Terminology	Definition	Source
Data Protection Approval	Procedure of applying to the national or local Data Protection Authority to report about the collection, storage and/or analysis of personal data for a specific task. Whether reporting the activity is enough or actual approval is granted depends on the respective data protection authority. The task leader is generally the legal owner of this procedure.	Initial DRIVER definition.
End-users	Individual person who ultimately benefits from the outcomes of the system.	ISO/IEC 25010:2011(en) Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — System and software quality models, 4.4.3.
Evaluation	Process of estimating the effectiveness, efficiency, utility and relevance of a service or facility.	ISO 5127:2017(en) Information and documentation — Foundation and vocabulary, 3.1.3.02.
Guidance Methodology	A structured approach from designing a Trial to evaluating the outcomes and identifying lessons learned.	Initial DRIVER definition.
Preparedness	The knowledge and capacities developed by governments, professional response and recovery organizations, communities and individuals to effectively anticipate, respond to, and recover from the impacts of likely, imminent or current disasters.	UNISDR: Terminology on Disaster Risk Reduction: A Technical Review. August 2015, p24.

²¹Until the Portfolio of Solutions is operational, the terminology is presented in the DRIVER+ Project Handbook and access can be requested by third parties by contacting coordination@projectdriver.eu.

Terminology	Definition	Source
Research ethics	The ethics of the planning, conduct, and reporting of research; this pertains in particular to rules and guidelines for the participation and protection of individuals taking part in the research activities.	D91.3.
Societal impact	Dimension of crisis management that refers to its unintended positive or negative impacts on different societal groups or society as a whole, as well as on its core values and societal principles as captured for example in fundamental rights, constitutional laws, but also in public debate.	Initial DRIVER definition.
Societal Impact Assessment	Dimension of crisis management that refers to its unintended positive or negative impacts on different societal groups or society as a whole, as well as on its core values and societal principles as captured for example in fundamental rights, constitutional laws, but also in public debate.	Initial DRIVER definition.
Trial	An activity for systematically finding and testing valuable solutions for current and emerging needs in such a way that practitioners can do this in a pragmatic yet systematic way.	Initial DRIVER definition.
Volunteer	[SV [spontaneous volunteer] Individual who is not affiliated with an existing incident response organization or voluntary organization but who, without extensive preplanning, offers support to the response to, and recovery from, an incident].	ISO 22319:2017(en) Security and resilience – Community resilience – Guidelines for planning the involvement of spontaneous volunteers, 3.1.

Annex 2 – Ethical Monitoring Questionnaire 3

Ethical Monitoring Questionnaire

This report (D913.3) is the third Ethical Monitoring Report in the project, and it follows the same general structure as the previous two. Please reply to the questions below as detailed as you can. The information collected will be used for the purposes of this deliverable only, and will not be shared with outside parties without permission. Any potential personal information will be kept confidential. Please contact PRIO for any questions.

Name/ partner organization:

Answering on behalf of the Sub-project: (please underline) Yes No

Answering based on input from WP-leaders: (please underline) Yes No

General questions

1. Within the scope of the activities of the Sub-project, have any of the WP's been in contact with local ethics committees or Data Protection Authorities?

a) If yes: please describe shortly the process. E.g. did any of the WP's encounter (unforeseen) problems or challenges (e.g. lack of answer, unclear guidelines, or unclear responsibilities)?

b) If no: do you foresee that such contact will be necessary for future activities? And do you expect any problems or challenges in relation to data protection requirements?

2. Has the template for “Application for Research Ethics Approval”, currently available on the CoW, been used for activities within the SP? Or are you aware of any plans to use it in the future?

3. Has the template for obtaining “Informed consent”, currently available on the CoW, been used for activities within the SP? Or are you aware of any plans to use it in the future?

4. How useful do you find the ethics guidelines provided in the CoW / Project handbook? E.g. are you missing any information with regards to research ethics? Is the information concrete enough? Are there any particular aspects that you would like to have guidance for?

5. In which way are the new EU General Data Protection Regulation (GDPR) requirements reflected upon in your institution’s DRIVER+ activities? Are you aware of any challenges partners within the SP have with regards to adhering to the new requirements?

6. Have any issues relating to data protection or research ethics come up for the work within the scope of this SP in DRIVER+ that you have not experienced before? Is there anything distinctive about DRIVER+? If yes, please provide a brief explanation.

- Are there other issues relating to research ethics in SP94 that you are aware of, and that should be tackled? E.g. are you missing a certain kind of information or support? Do you want information/support in a different format?

SP 5 – Impact, engagement and sustainability

- When realizing the CMINE, describe briefly how the collected personal data will be processed and protected?

- Are there other issues relating to research ethics in SP95 that you are aware of, and that should be tackled? E.g. are you missing a certain kind of information or support? Do you want information/support in a different format?