



D1.3 Report on exploratory meetings with relevant policy/standard makers

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1. SUMMARY

While robots should be safe, robot regulatory frameworks do not always frame technology development accurately. LIAISON investigates to what extent compliance tools, in this case, the COVR toolkit, could be used as data generators for policy and standard makers to unravel an optimal regulatory framing for existing and emerging robot technologies and improve robot technology overall safety and market entrance ease. As such, LIAISON aligns with the overall COVR goal to reduce complexity in safety certifying robots.

New technologies sometimes question and challenge existing norms, breathing into existence the need for legal change. While the pace of technology dramatically accelerates, however, legal responsiveness does not always follow as a consequent step. As no formal communication process between robot developers and regulators from which policies could learn has been established yet, a stepback mechanism for robot governance as novel as that introduced by LIAISON is yet to be introduced to all stakeholders involved, in particular robot developers and policy/standard makers. To prove the feasibility and added value of the creation of this link between robot developers and relevant regulators, for the LIAISON project, we focus on three particular standards: ISO 13482:2014 on personal care robots, IEC 80601-2-78:2019 on rehabilitation robots, and EN ISO 18497:2018 on agricultural machinery and tractors. The policy and standard makers involved for this purpose represent both private standardisation organisations and the European Commission.

This report presents the results, action points, considerations, and conclusions derived from three formal meetings held with these policy and standard makers to gauge their responses to LIAISON as a new robot governance mechanism, primarily focusing on its feasibility, usefulness, and acceptability. While it is still too early to determine with total certainty, overall LIAISON can be considered a practical and valuable means to improve robot regulation, both in terms of linking robot developers and policymakers and in terms of connecting the broader ecosystem of public policymakers (to harmonize current standard efforts), standard organizations (to ease and make sound safety compliance processes), robot developers/manufacturers (to incorporate legal requirements into the design of the technologies), and end-users (to have a voice in this whole process), which is currently not sufficiently aligned.

2. INTRODUCTION

COVR stands for "being safe around collaborative and versatile robots in shared spaces", and is a European H2020 Project which aims to reduce the complexity in safety certifying cobots significantly. In this respect, the project has developed the COVR Toolkit, an online tool that guides developers in their legal compliance process, from helping them find relevant technical standards/directives/protocols to guide them on performing a risk assessment.

Assessing risks through experimentation is essential to ensure robot safety and compliance with existing norms. However, standards do not always frame technology development accurately. LIAISON investigates to what extent compliance tools (tools that help comply with the legislation, such as the COVR toolkit) could be used as data generators for policy and standard makers to unravel an optimal regulatory framing (including change, revise, or reinterpret) for existing and emerging robot technologies. LIAISON is a crucial stepback mechanism to help align robot and regulatory development and improve robot technology's overall safety and market entrance ease. As such, LIAISON aligns with the overall COVR goal to reduce complexity in safety certifying robots by providing policy and standard makers with the necessary knowledge about legal inconsistencies, new categories, or new safety requirements (including psychological) to update existing frameworks where necessary and to ensure that the next generation of robots is 'safe' to the full extent of the word. In this way, LIAISON contributes to the COVR mission by adding a link to public and private regulators to complete the cobot value chain.

To prove the feasibility and added value of creating this link between robot developers and relevant regulators, for the LIAISON project, we focus on three particular standards: ISO 13482:2014 on personal care robots, IEC 80601-2-78:2019 on rehabilitation robots, and EN ISO 18497:2018 on agricultural machinery and tractors. To ensure all parties are heard, LIAISON aims to include robot developers, policy and standard makers, and interested groups (e.g., ANEC). In this project, we held different formal meetings with relevant policy and standard makers at an early stage of the project to explore how they perceive LIAISON and how they can contribute to LIAISON in helping relevant policy and standard makers frame robot development adequately. The policy and standard makers involved for this purpose represent both private standardisation organisations and the European Commission.¹ This report sets the scene in section 2 with an overview of the background of and reasons leading to LIAISON, followed by the methods used for the exploratory meetings and the goals and objectives of the exploratory discussions with the relevant policy and standard makers. Finally, we provide an overview of the exploratory meetings held - presenting the meeting notes, action points, considerations, and conclusions.

¹ Personal names are anonymised for the purpose of this report.

3. LIAISON

3.1. BACKGROUND

“The art of progress is to preserve order amid change, and to preserve change amid order” – Alfred North Whitehead.

Robot technology is one of the many technologies that challenge the regulatory framework in various ways, including ethics and security for responsible innovation, privacy, and responsibility allocation. As products, robots widely differ in embodiment, capabilities, context of use, intended target users, and many regulations may already apply to them. Having tools such as the COVR Toolkit can be of help. However, new applications may not fit into existing (robot) categories, legislation might be outdated and confusing categories, and technology-neutral regulations may be hard to follow for developers concerned about their particular case. A recent open consultation launched by the European Commission, for instance, acknowledges that current European Harmonized Standards do not cover areas such as automated vehicles, additive manufacturing, collaborative robots/systems, or robots outside the industrial environment, among others (Spiliopoulou-Kaparia, 2017). In light of all the issues this technology arises, part of the literature accentuates the need for an issue manager. Marchant and Wallach (2015) proposed the creation of "Governance Coordinating Committees (GCC)" for the governance of emerging technologies like AI.

Furthermore, the European Parliament proposed creating a European Agency for Robotics and Artificial Intelligence early in 2017, and Schatz put forward the result of an emerging technology policy lab within the US general services administration in 2018. However, what lacks in robot governance is a backstop mechanism that can coordinate and align robot and regulatory development (Fosch-Villaronga & Heldeweg, 2018). Overlooked in the latest review of "the grand challenges of science robotics," this challenge has already been raised in the literature, albeit only more recently (Yang et al. 2018), and relates to the idea of how policies can frame the rapid development of robotics. LIAISON contributes to these approaches by proposing the *modus operandi* of issue managers, if they were ever to exist, and revolves around the following main research question:

Could the use of compliance tools, such as the COVR Toolkit, as data generators for robot policy purposes reduce emerging robot governance complexity?

LIAISON envisions an iterative regulatory process for robot governance, a theoretical model that represents a practical step forward in the coordination and alignment of robot and regulatory development, called the Iterative Learning Governance Process (ILGP). This research project conceives an effective way to extract compliance and technical knowledge from compliance tools (tools that help comply with the legislation such as the COVR toolkit) and direct it to policy and standard makers to unravel an optimal regulatory framing (including change, revise, or reinterpret) for existing and emerging robot technologies. This process will bring clarity to what regulatory actions policy and standard makers have to take to provide compliance guidance, explain unclear concepts or uncertain applicability domains to improve legal certainty, and inform future regulatory developments for robot technology use and development at the European, National, Regional, or Municipal level. As such,

LIAISON is a crucial stepback mechanism to help align robot and regulatory development and improve robot technology's overall safety and ease of market entrance.

The primary outcome of the LIAISON Research Project will be the design concept for liaising robot development and policymaking to increase overall robot safety. This design concept will further develop the *Iterative Regulatory Process for Robot Governance*, which was ideated as a theoretical model that links technology impact assessments to legislative ex-post evaluations via shared data repositories intending to create evidence-based policies that can serve as temporary benchmark for future and new uses or robot developments (Fosch-Villaronga & Heldeweg, 2018, 2019). Part of the 'technical challenge' is to put such a theoretical model into practice and in the context of the COVR project. Explained further in figure 1 in the Annex (Fosch-Villaronga & Heldeweg, 2018), such iterative regulatory process for robot governance stresses that in the light of a new robot development or use, and after assessing all the impacts (and incorporating the findings into the robot itself), it is essential to compile all the Regulation-to-Technology uncovered barriers and constraints that do not allow the roboticists to proceed with their creation. Having collected those constraints in a Technology-to-Regulation manner, the regulator can act thereupon supported by the accountability tool's information, in this case, the COVR Toolkit.

The expected project results will complement the existing knowledge on the 'ethical, legal, and societal (ELS)' aspects of robotics by providing clarity on how to address pressing but still uncovered safety challenges raised by robots, and represent a practical, valuable tool to advance social goals in a robotized workplace. Overall, advances in safety robot legal oversight will provide a solid basis for designing safer robots, safeguarding users' rights, and improving the overall safety and quality of efficiency delivered by robots.

3.2. DELIVERABLE 1.3. REPORT EXPLORATORY MEETINGS WITH RELEVANT POLICYMAKERS

LIAISON aims to link robot developers to relevant policy and standard makers through an Iterative Learning Governance Process supported by data generated through accountability tools, in this case, the COVR Toolkit. As no formal communication process between robot developers and regulators from which policies could learn has been established yet, a stepback mechanism for robot governance as novel as that introduced by LIAISON is yet to be introduced to all stakeholders involving robot developers and policy and standard makers. Deliverable 1.3. of the LIAISON Research Project aims to gauge the responses to LIAISON as a new robot governance mechanism among policy and standard makers. Considering the specific focus on the three standards mentioned above (i.e., ISO 13482:2014, IEC 80601-2-78:2019 and EN ISO 18497:2018), for this purpose, LIAISON set three exploratory meetings with relevant policy and standard makers.

3.2.1. METHOD

LIAISON engaged with relevant standard makers to gain the necessary insights and information and further the LIAISON Research Project and its objectives. We held two online exploratory meetings during which we discussed the feasibility, usefulness, and acceptability of LIAISON to align robot and regulatory development and improve robot safety standards and legal frameworks from the perspective of the relevant standard makers. For a further overview of the meeting agenda, see tables 1 and 2 (annex).

3.2.2. GOALS & OBJECTIVES

Involving relevant standard makers at an early stage of the project and through the method mentioned above enabled us to identify how standard makers perceive LIAISON in terms of feasibility, usefulness, and acceptability. Furthermore, the exploratory meetings allowed us to explore synergies and establish possibilities for further cooperation throughout the LIAISON Research Project and in the longer term.

4. EXPLORATORY MEETINGS

4.1. MEETING NOTES

3.3.1. EXPLORATORY MEETING 1 | PRIVATE POLICYMAKERS (12-01-2021)

Regulations are often written in high-level legal language and focus mainly on legal requirements. As a result, regulations are often not sufficiently complete to cover all safety requirements concerned with the development of robot technologies. These safety requirements, however, are provided through international standards, which are frequently updated. This in contrast to regulations, which remain constant for a more extended period and are generally technology-neutral.

Standards are written in a more technical language, thereby complementing regulations. Also, standards are usually harmonized under the legislation [reg. 1025/2012](#)², which governs the harmonization process of standards. Nevertheless, currently, such harmonization is lacking. The EC applies a rigorous interpretation of this regulation, making it very hard to harmonize standards (although there is already some dissent, e.g., Germany).

Out of this meeting, we realize the existence of a large ecosystem involving public policymakers (link: harmonization), standard organizations (link robot developer/safety), robot developers/manufacturers, and end-users, which is not aligned. This shows the importance of bringing together all these stakeholders to align their efforts into making current and future robots safe to use.

Regulations do not give the concrete technical requirements needed for robot development. Legal requirements are essential, but they do not provide further guidance in product development. LIAISON tries to understand the two normative forces in framing robot technology and how advancements in robot technology are currently pushing these frameworks towards improvement.

While LIAISON's exact usefulness and feasibility from the perspective of standardization are difficult to express at such an early stage, it is clear that LIAISON can be beneficial in certain regards. Robot manufacturers have a set of many standards that they use in developing and manufacturing their products. Together, these standards will cover all regulations, but each one individually covers only a part. As robot manufacturers ought to prove that they are compliant with each of the applicable standards, they need to know which standards apply to their products. Especially for new robot manufacturers (a more specific version of), the COVR Toolkit could be very useful and valuable (taking inspiration from, e.g., the [US Regulatory Robot](#)).

While there is much work on and talk about robots, AI, and machine learning, there is no convergence on standards, no coherent understanding of these concepts, and no cohesive

² See Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance.

definition for each of them. Robot developers need more guidance within this context, and there should be alignment between national and international, private, and public initiatives.

Beyond, new developments in robot development lead to new policy and regulatory needs. It would be helpful for ISO and other regulators to obtain information from robot developers to improve and update current standard frameworks.

4.3.2. EXPLORATORY MEETING 2 | PRIVATE POLICYMAKERS (13-01-2021)

In the EU, a wide variety of regulations and standards covering medical safety requirements for robotic technologies is in place. This was one of the impeding factors for ISO as it was challenging to include both medically and machinery-related topics in the standard. As a result, the focus of ISO 13482:2014 focuses exclusively on non-medical applications. Further activity and cooperation with the IEC led to the inclusion of medically related topics, resulting in other standards (e.g., rehabilitation and surgery).

It is significantly challenging to persuade ISO (especially TC299) to bring an ethical dimension into the committee and broader community compared to the efforts held by IEEE. Although there is much technical expertise within ISO/TC299, one of the main challenges is that there is only very little attention for ethical aspects.

The revision of ISO 13482:2014 has been started, and it is now in progress. LIAISON could be very relevant within this context. It would allow for a broader picture of the inconsistencies and gaps in ISO 13482:2014 currently experienced by robot developers and manufacturers. Further cooperation between ISO/TC299/WG2 and LIAISON could, therefore, be very relevant.

Within this context, there are two possibilities:

- Come on board as an official expert in the process: communicate with the national standardization organization (NEN), so they can nominate to ISO/TC299/WG2.
- Come on board as an observer.

Cooperation between LIAISON and ISO/TC299/WG2 could also be valuable to LIAISON to get more insight into what needs to be revised in ISO 13482:2014.

Some general points and current thoughts on ISO 13482:2014:

- The standard is broad at the moment.
- The structure of the standard requires further improvement.

3.3.3. EXPLORATORY MEETING 3 | PUBLIC POLICYMAKERS (05-02-2021)

There is a suspicion within the EC that technologies and regulations do not sufficiently align, and improvement is needed. However, the EC is a very complex organization that ensures the rule of law in Europe. Since the EC is divided in multiple Directorate Generals where domains and competencies are divided, communication between the different parties is very difficult. Currently, the EC is conducting a study on landscaping the standards on safety of autonomous robots controlled by AI. The details of the study, as elaborated in the the terms of reference of the study, are provided below:

Study on Trends and Development in Artificial Intelligence: Standards Landscaping and Gap Analysis on the Safety of Autonomous Robots Controlled by Artificial Intelligence

Objectives:

‘The objective of this study is to provide results necessary to support the implementation of a European AI strategy. In particular, the study will touch on the many ways to apply AI to increase cognitive capacity levels and autonomy of robots of any kind, with the exception of autonomous vehicles on public roads.

The study will provide an overview in which specific application areas of AI-controlled advanced robotics, new safety standards would need to be developed in order to facilitate the rollout of this technology. The study should take the ongoing regulatory work the Commission is conducting with respect to the product safety legislation relevant to AI products and systems, which may have an impact on the developments of standards in this area, into account.’

Application sectors (focus is only on safety issues and not on autonomous vehicles):

- medical (healthcare and rehabilitation including prosthetics);
- domestic robots (in particular robots designed for personal-care);
- industrial (in particular wearable and collaborative robots); and
- field robots (in particular agriculture applications).

LIAISON could be helpful and valuable in improving the communication between all stakeholders involved in the development and regulation (be it through public or private bodies) of new technologies. The focus of the LIAISON Research Project is on testing the model of an iterative governance model by explicitly looking at standards. While this means that EU Regulations and Directives are not the main focus of the project, having fit standards in place is essential in lawmaking and makes the related procedures much more effective and efficient.

To create an optimal regulatory framework for new technologies, the EC needs to communicate with society better. A platform based on the model proposed by LIAISON, especially the idea of a shared data repository, could be beneficial and valuable in this respect. **Note:** such a platform ought to be fair by design (all stakeholders must be fairly represented), and the collected data must be ranked and rated according to their relevance for policymaking purposes. While there is thus room for a model such as that proposed by LIAISON, there are many complex issues involved in policymaking that require attention when establishing and implementing the proposed model (e.g., Dustbot, see Salvini, Laschi, & Dario).

4.4. ACTION POINTS

The exploratory meetings with the abovementioned standard makers led us to come to the following main action points:

MAIN ACTION POINTS	
MEETING	ACTION POINT
Meeting 1	<p>Further, discuss and explore the possibility to build and strengthen cooperation with the Dutch Standardisation Organisation (NEN) for the LIAISON Research Project.</p> <p>Explore the possibility to include public policymakers in the LIAISON Research Project to touch upon and further discuss the subject of harmonization within the context of robot regulation.</p>
Meeting 2	<p>Further, discuss and explore the possibility to build and strengthen cooperation with the ISO/TC299/WG2 and CLAWAR for the LIAISON Research Project.</p>
Meeting 3	<p>Further, discuss and explore the possibility to build and strengthen cooperation with the European Commission for the LIAISON Research Project.</p> <p>Further explore the possibility to establish contact between LIAISON and the tenderer behind the Study on Trends and Development in Artificial Intelligence: Standards Landscaping and Gap Analysis on the Safety of Autonomous Robots Controlled by Artificial Intelligence (e.g., for involvement in their workshop of the 4th of March 2021).</p>
Meeting 1, 2 & 3	<p>Further, cooperate with the involved policy and standard makers to shape and refine the surveys included in feedback loop 1. More specifically, by providing us an insight into the inconsistencies and gaps in the relevant standards already established by them, and any specific questions on inconsistencies and gaps they find necessary to include in the surveys included in feedback loop 1 (see figure 2, annex)</p>

4.5. CONSIDERATIONS

Following the exploratory meetings, we consider the following:

- Take part in ISO/TC299/WG2 either as a full member through the official nomination procedure by the official national standardization organization (NEN) or as an observer member.
- Further, extend our cooperation to include CLAWAR to establish a pool of respondents to participate in the feedback loops that form part of the LIAISON mechanism (see figure 2, annex).
- Explore possibilities to be more closely involved in ongoing activities and projects of the EC in related areas, and consider opportunities to establish a working group on Iterative Learning Governance processes with the EC and other relevant stakeholders.

4.6. CONCLUSIONS

Concerning the feasibility, usefulness, and acceptability of LIAISON from the perspective of standard making and standard makers, the exploratory meetings have led us to conclude as follows:

CONCLUSIONS	
MEETING	MAIN CONCLUSION
Meeting 1	<p>Within the context of robot regulation, there is a large ecosystem involving public policymakers, standard organizations, robot developers/manufacturers, and end-users, which is not aligned. The lack of relationship is evident in many moments. For instance, standard organizations do not seek proactive engagement with user groups or patient organizations. Moreover, joining these standardization efforts comes with a price, privatizing stakeholder participation and user rights. The mechanism introduced by LIAISON shows the importance of bringing together all these stakeholders to align their efforts into making current and future robots safe to use that aligns more with how the public law ensures companies and developers respect European fundamental rights.</p> <p>While LIAISON's exact usefulness and feasibility from the perspective of standardization are challenging to express at such an early stage, it is clear that LIAISON can be beneficial in certain regards. Robot manufacturers have a set of many standards that they use in developing and manufacturing their products. Together, these standards will cover all regulations, but each one individually covers only a part. As robot manufacturers ought to prove that they are compliant with each of the applicable standards, they need to know which standards apply to their products. For new robot manufacturers, a more specific version of the COVR Toolkit could be instrumental and valuable (taking inspiration from example, the US Regulatory Robot). LIAISON can also add to this by providing a mechanism for improved and continuously improving robot regulation.</p>
Meeting 2	<p>Establishing a good relationship and cooperation between ISO/TC299/WG2 and LIAISON could be helpful and valuable. On the one hand, ISO/TC299/WG2 could provide LIAISON with the necessary input from standard making. On the other hand, looking at its goal, LIAISON could offer WG2 the relevant knowledge on inconsistencies and gaps in ISO 13482:2014 from the perspective of robot developers.</p> <p>A potential pitfall of the LIAISON Research Project could lie in the low response rate from the community of robot developers. Success in this regard depends on communication and outreach.</p>
Meeting 3	<p>To create an optimal regulatory framework for new technologies, the EC needs to communicate with society better. A platform based on the</p>

	<p>model proposed by LIAISON could be beneficial and valuable in this respect. LIAISON could be instrumental in improving the communication between all stakeholders involved in the development and regulation (be it through public or private bodies) of new technologies.</p> <p>The focus of the LIAISON Research Project is on testing the model of an iterative governance model by explicitly looking at standards. While this means that EU Regulations and Directives are not the main focus of the project, having the right standards is essential in lawmaking and makes the related procedures much more effective and efficient.</p>
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6. ANNEX

Iterative regulatory process as developed by Fosch-Villaronga, E., & Heldeweg, M. (2018). "Regulation, I presume?" said the robot—Towards an iterative regulatory process for robot governance. *Computer law & security review*, 34(6), 1258-1277.

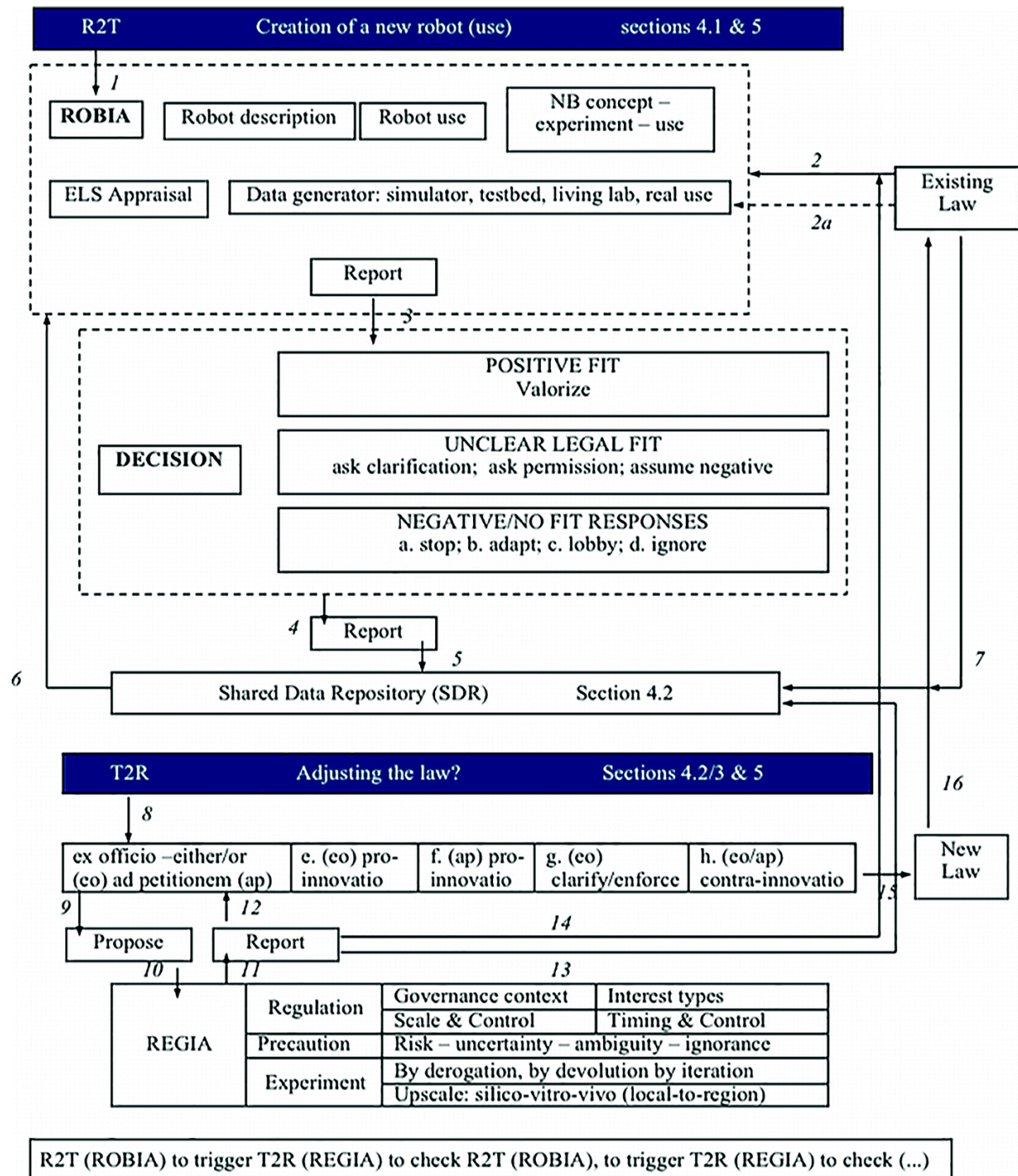


Figure 1: Preliminary iterative process for robot governance³

³ As regards the meaning of arrows: #1. signifies that upon the initiative to develop a new robot (use) the ROBIA process commences; #2 and #2a are about information about existing law/legal space being fed into the ROBIA fit to regulation process; #3 outcomes of ROBIA are reported to initiators to decide if and if so, how the development process can be continued; #4 and #5 concern reporting the decision and making information available to the SDR system; #6 is about how (changes in) information in SDR are a source of information to the ROBIA process – as shared learning; #7 is about information about existing law with relevance to robotics is also part of the shared data in SDR (#2 is about specific legal information to a specific

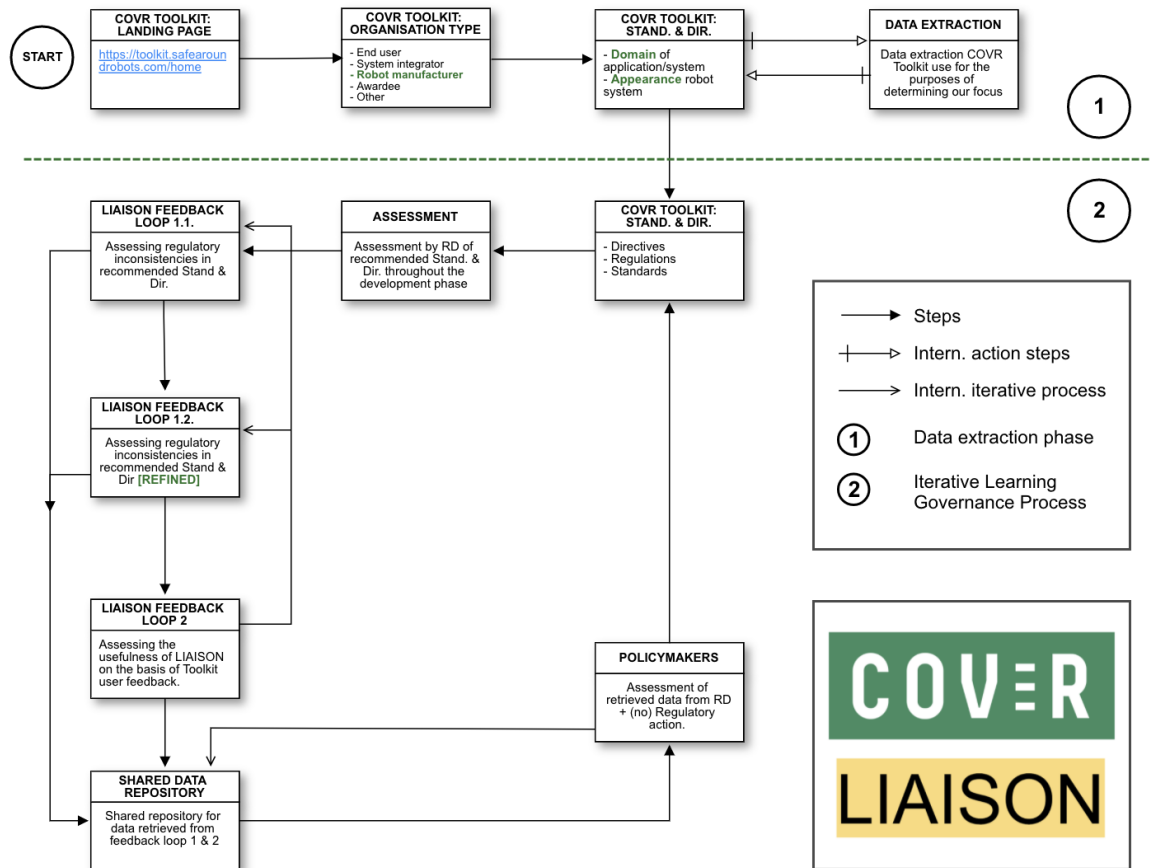


Figure 2: LIAISON Research Project mechanism

ROBIA procedure; #7 about the general updating of legal info in SDR); #8 expresses that upon R2T events a process about possible legal adjustments is started; #9 and #10 when it is decided (ex officio/ad petitionem) that some legal change may be called for, a (basic) proposal is formulated whereupon the REGIA procedure is initiated; #11 and #12 show that outcomes of the REGIA procedure are reported back and feed into the decision on legal change; #13 Information in the report is also fed into SDR to update regulatory information; #14 REGIA report can feed ROBIA without passing via the Existing law> box, as the REGIA report will say something about pros and cons of possible legal change, but should that change follow, then this will communicate via the <New law> box; #15 signifies adjustments in the law; #16 expresses that new law changes and becomes part of existing law.)

MEETING AGENDA		
TOPIC		TIME
Personal introductions		+/- 5 mins
Presentation LIAISON Research Project		+/- 10 mins
Explanation LIAISON mechanism		+/- 5 mins
Usefulness & feasibility LIAISON	Initial thoughts on usefulness and feasibility LIAISON	+/- 15 mins
	Standard making, inconsistencies and current approach in standard making	
	Opportunities and potential pitfalls LIAISON	
Exploring synergies	How can LIAISON be of help?	+/- 15 mins
	How can policy/standard makers be of help?	
	Views on long-term cooperation and feasibility	
Moving forward + wrap-up	Next steps LIAISON	+/- 15 mins
	Action-points meeting	
	Follow-up	

Table 1: Meeting agenda exploratory meetings 1 and 2 with representatives of private standardisation organisations.

MEETING AGENDA		
TOPIC		TIME
Personal introductions		+/- 5 mins
Presentation LIAISON Research Project		+/- 10 mins
Explanation LIAISON mechanism		+/- 5 mins
Usefulness & feasibility LIAISON	Initial thoughts on usefulness and feasibility LIAISON	+/- 15 mins
	EU legislation and safety standards uncovered challenges & harmonisation gap	
	Opportunities and potential pitfalls LIAISON	
Exploring synergies	How can LIAISON be of help?	+/- 15 mins
	How can policy/standard makers be of help?	
	Views on long-term cooperation and feasibility	
Moving forward + wrap-up	Next steps LIAISON	+/- 15 mins

	Action-points meeting	
	Follow-up	

Table 2: Meeting agenda exploratory meeting 3 with representatives of the EC.