

Fact sheet on public deliverables analysis



AAL Projects are carried out in increasingly complex environments where science and technology progresses are challenging the traditional way to conduct research and development (R&D) projects. Furthermore, the European partners in a Consortium bring together multidisciplinary stakeholders from different countries with different practices regarding ethics and privacy but also different stages of Technological Readiness Levels (TRL).

The fact that AAL projects involve testing by end-users of innovative products and services development, for the improvement of the quality of life of the ageing population, carries important ethical and European legal obligations. This is particularly relevant with the obligation to apply the recent European Data Protection Regulation (GDPR 2018) at many stages of AAL project work packages which were formerly not foreseen, such as data protection management processing in several types of end products and services. Not complying to GDPR, business development run the risk to fail their future success and entry to the market.

From the first Calls of AAL up to today, one can observe a relevant improvement in the quality of ethical requirements. From little material and few projects displaying Consent forms to the latest projects with systematic sections and consent forms. This progression demonstrates the increasing importance given to ethics and now legal obligations in research and innovation. Those aspects are and will be more and more crucial as science and technology progress rapidly into connecting and interconnecting innovation and technologies with areas such as Internet of Things, Artificial Intelligence, automated decision-making or tracking/profiling systems.

...in terms of cooperation in an AAL project General requirements by AAL Programme

Ethics and Privacy issues are fundamental not only to demonstrate a high quality of R&D procedures in human – machine interactions, but are also to guarantee that the findings and output of a programme and its projects are sound, scalable, sellable and suitable for the market, i.e. compatible with the EU regulations and safety of data protection. This is particularly important when consortia involve international partners which do not comply with EU regulations or when the product intended for the market includes components which are incompatible with EU regulation (e.g. voice recognition through US Amazon Echo or Alexa in projects).

...in the overall domain

From the beginning of the AAL programme, projects format has evolved into more complex ethical and privacy/data protection aspects requiring new measures, which are related to specific aspects, such as:

- (i) the type of Call – from a “topic-led” to a “challenge-led” to a completely “open” one;
- (ii) the tendency to push R&D project closer to the market with stronger regulations;
- (iii) the type of innovation that emerges where personal data can be identifiable or re-identifiable posing data protection risks (i.e.: voice/facial recognition, tracking, health care data in/out of institutions, home monitoring from outside institutions/persons, etc.);
- (iv) the older population typology or level of digital illiteracy, or medical condition/impairments (i.e. lack of discernment, cognitive deficiencies).

This super-composition of different ethical and data privacy frameworks has at times brought unclarity in the ethical and GDPR standard requirements that AAL reviewers should apply in Mid-Term and Final Reviews. Those situations were mainly resulting from a) All-in-one solutions with multiple AAL projects, b) new segments of R&D with new requirements (e.g. web platform services and/or payment), c) disruptive innovations bringing new ethical issues (e.g. voice/facial recognition), d) challenging projects with multiple stakeholders private/public with sensitive data and the need of multiple consent forms.

Main findings from the analysis of the public deliverables



Over the years, AAL projects have increasingly improved the development of a coherent framework to address the main ethical issues and provide consent forms. In parallel, AAL programmes have steadily augmented the complexity of the Calls by opening consortium to new stakeholders, new transdisciplinary/convergent themes and challenging solutions. This complexity has enriched and made significant changes in the way ethics and informed consent issues are described and managed in more details in the latest years. With the entry into force of the GDPR (December 2018), the need to consider in a new perspective AAL programmes and Calls as well as personal data protection and management is clear. Some of the main finding in the analysis of the public deliverables related to ethics are:

Ethics in general

From the deliverables reviewed, one can observe that in Europe, Ethics approval procedures and requirements are well applied. However, the procedures differ at the following levels:

- from country to country;
- from institutions to institutions private/public, such as hospitals, working settings, retirement homes;
- between disciplines such as medicine/clinical, health care, home care, retirement homes, community;
- depending on methods/policies used: clinical studies/medical settings has usually a clear and specific procedure to respect with ethical committees, country and/or national ethical committees, etc.;
- at different stages of R&D: interview with end-users, interview with institutions, testing with workplace, testing with communities.

Ethical Boards /Advisory Boards

- several but not all projects propose an ethical board;
- the way the ethical board is constituted or managed does not follow any specific rule and this may lead to conflicts of interest.

Informed Consent and Consent Forms (CF) - A pillar of Ethics and GDPR

- most projects apply signed consent forms;
- consent forms have multiple formats in the different projects;
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- some projects apply them to multiple groups: testers, institution managers, proxies, workplace monitoring (i.e. projects with surveillance systems or light therapy in day/night shiftwork, etc.);
- are applied at different timelines of the project such as double testing, reiterative testing, manager interviews;
- are not uniformed;
- are not fully conform to GDPR regulations after it entered into force in 2018.

Note on GDPR Obligations on personal data/privacy management in AAL projects after 2018

Consent Forms under GDPR: Obligation to inform and seek permission to include the participant in a project (Articles 4(11) and 7 GDPR).

- Considering that GDPR entered into force in 2018, most of the public deliverables are from previous calls, when new regulation was not in force yet;
- Given the privacy issue in GDPR are much more complex and broader in scope than the sole consent form, the projects were often addressing the end-user data collection and less the privacy data management system throughout the project until end product ready for the market. After expert review, they have however well integrated it in a more comprehensive way;
- very few projects have given attention to publicly explain in a transparent way how the personal data collected through the innovation (directly or indirectly) will be managed and handled over time; they have mainly addressed it in a punctual or scarce way, where older subjects were not fully informed about it on a website, App or other product services according to GDPR (i.e. how data is processed, stored, encrypted or not, re-identifiable or not, deleted or not, for how long.);
- The challenge of GDPR concerns in particular data management and procedures of specific innovations: a) the type of technology (such as tracking or voice recognition), b) to the web-platforms selling or proposing networking of consumers c) to financial management of services with online banking/payment, d) involving sensitive data management issues i.e. health care data or workplace data, d) personal data such as images, videos or tape recorders clearly submitted to ethical CF and copyrights regulations.



Ethics in general

The fact that the AAL unique programme model has been increasingly calling for project collaboration between very different multi-stakeholders from public and private sectors (e.g. research, technology/innovation, end-users, NGOs, business, market) has led to a challenging situation for harmonising ethical and privacy issues. Therefore, some projects have had to submit many different consent forms to different groups involved in the project to respond to the ethical requirement (as in the case of a 2014 Call project where 4 different consent forms for testing were used - administrators, test persons, local emergency, in case of disappearance).

Ethical Boards /Advisory Boards

Projects that propose to set up ethical boards should be informed and required the following as basic ethical rules:

- Constitution of the ethical board rules: they must follow clear and transparent rules;
- Avoiding conflict of interest: to ensure that members of the board are independent from the research partners and institutions in the consortium;
- Regular and transparent reports are made along the project and included in AAL Reviews.

Privacy – Personal Data Protection and Management

The importance of privacy and data protection was underestimated in several AAL projects. Today, it has become clear that product and services that do not comply early in the business development plan with ethics and GDPR have a strong risk of negative impact or failure when entering the market.

Privacy and data protection in all aspects of scientific research is increasingly required, especially in R&D products and services that manage/track "sensitive personal data", and is a core aspect of the success route to the market (see final recommendation explanation).

This is especially important when considering products and services on open platforms or Apps, where older end-users can be the most vulnerable group prone to abuse, such as those with fluctuating cognitive deficiencies or less digital and rights literacy. There is therefore:

PROGRAMME

- The need to educate researchers and end-users about GDPR;
- The need to elaborate a level of requirement depending on TLR products and technologies, for example, displaying clearly sensitive data management processes and procedures.

Overall –Ethics and GDPR

The need for harmonising Ethics and the GDPR

- Templates and models of consent form, sensitive data, information to consumers, etc. that are conform to the GDPR could be included in information documents on ethics which can be adapted to multiple groups and stakeholders: administrators, end-users, institution managers, proxies, work place monitoring (i.e. project with light therapy systems/surveillance systems at the workplace);
- Disclaimers are a solution for platform and solutions that are not ready for the market or targeted to be plug ins to more sophisticated systems
- TRL is different in different countries with different levels or GDPR requirements;
- Some technologies and innovative services require more scrutiny in applying GDPR and CF protocols, in particular: tracking devices, identifiable persons through voice/face/etc. recognition, monitoring and surveillance, health care settings, medical data.

Opportunities deriving from criticalities



Given the recent European GDPR regulation (2018) on personal data protection and data management in all areas of R&D, science and technology, regardless of where their data is processed, the AAL Programme and projects have the opportunity (and the indirect obligation) to get up to date with the optimal application of the GDPR at each stage of the project work packages when relevant as well as to the current market requirement before projects enter into the market phase.

Thus, aspects such as personal data management, end-user/technology, data monitoring, web platform transparency with ethics and regulations need to be considered at each step of the AAL project, whatever the innovative system, private/public, products/services, national/international.

Focusing on integrating GDPR-compatible data privacy and intellectual property, as well as disclaimers and legal responsibility clearance are an imperative for safe/clean/secure innovation and technology development today. AAL projects have an opportunity to be leading edge and be GDPR-ready for the market.

It is recommended that the AAL programmes and projects consider developing an **"Ethical and GDPR Resource Center"** which would include basic documentation/information, procedures and templates for guiding the programme and the participants (see below). It is an opportunity to establish a more coherent ethical and data protection framework within the AAL Programme and projects. This would bring a more coherent picture and facilitate the implementation of solutions and products.

There is an opportunity for projects to upscale and improve the quality of their output and final product. ***For that, basic documentation for AAL projects could include the following:***

- ***Document/information:*** AAL guideline on GDPR, Ethics, Consent Form Templates which would harmonize AAL requirement between countries/internationally, between institutions, between disciplines, between different R&D methodologies of data management and at different stages of entry to the market;
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- there are possibilities of harmonizing different ethical/privacy and personal data management requirements which need different guidelines and novel approach such as case studies, blogs, etc.;
- *Specific information on GDPR personal data management/monitoring for AAL projects*, in particular for "sensitive data" and institutions handling of "sensitive data" are challenging, yet the need to be considered in future projects and programmes. This applies in particular (a) for the following type of technological innovations: service to consumers through platforms/Apps, automated decision-making, mobile data, data-mining techniques, big-data analytics and artificial intelligence; (b) data processing methods (pseudonymisation, anonymisation and re-identification) which are at high ethics risks to infringe the rights and freedoms of older subjects. (c) tools and technologies for data management and storage will also require consideration (i.e. storage platforms, service providers, mobile technologies, Apps, payment services, etc.);
- AAL projects would be advised to write a clear DISCLAIMER regarding any subsequent consequences of AAL projects not being compliant with the EU regulations.

Therefore, there is a clear opportunity for AAL to play a leading role in the reflection on ethical and data privacy/GDPR issues in the growing domain of innovation and older persons.

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