An International Clinical Validation of Radiomics Artificial Intelligence for Breast Cancer Treatment Planning

Multi-stakeholder engagement and social innovation: from engagement to consensus

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Multi-stakeholder engagement and social innovation: from engagement to consensus

RadioVal is a European Research and Innovation Action, funded under the Horizon Europe Framework (Grant Agreement No. 101057699). The project implements a multi-centre, multi-continental and multi-faceted clinical validation of artificial intelligence solutions for breast cancer treatment, specifically on radiomics-based prediction of neoadjuvant chemotherapy treatment response. The project will develop a comprehensive and standardised methodological framework to enable multi-faceted, transparent, and continuous evaluation and monitoring of the radiomics tools over time. The RadioVal study will be implemented through a multi-stakeholder approach, considering clinical and healthcare needs, as well as socio-ethical and regulatory requirements from day one.

The multi-stakeholder engagement activities follow a social innovation framework developed from the start of the project in September of 2022 (described in D1.1 Social innovation framework[1]). After a thorough stakeholder mapping activity, we established procedures on how to optimally involve all relevant stakeholders, ensuring that their needs, wishes, fears and challenges are considered during the development of the RadioVal solutions. The first social innovation session– the "science cafes" – was designed to lead to a set of requirements for the design and implementation of the RadioVal tools. In the second round – "ideation workshops" – different techniques were applied resulting in a framework for contextual implementation of the RadioVal tools. Additionally, in this second round, sessions with healthcare professionals and AI developers were conducted around the FUTURE-AI guidelines. The third and final round of sessions – Prototype deliberation – consisted of a presentation of low- and high-fidelity mock-ups to the stakeholders to evaluate, validate and comment the captured requirements, as discussed further in this document. An Open Call for Experts was launched in the media channels of the project as well as through direct contacts of the consortium members to increase the geographic and expertise diversity of the participants. Seventeen experts external to the project consortium, including ethicists, health authorities' representatives, and clinicians, from 11 different countries, were invited to join the second and third rounds of the multi-stakeholder sessions.

The outcomes of the various Social Innovation Sessions were described in detail and will later be published in an official project deliverable D1.2: Multi-stakeholder requirements for radiomics evaluation (slated for a release in August of 2024), as well as integrated in scientific publications. These reports are the primary source of information for the definition of Stakeholder Requirements in the RadioVal project. But before providing additional details on this process, we must take a step back and shortly describe the project's requirements engineering framework.

Requirements elicitation

In RadioVal we use Requirements as a framework for translating the needs, wishes and desires of stakeholders to a language that can be understood by the technical partners in the Consortium. We focus on eliciting clinical, socio-ethical, legal, and regulatory requirements through a combination of the social innovation sessions described earlier, desk research, and workshops with patients. There is no single, unifying definition of what a Requirement is. In RadioVal we see a requirement as "a usable representation of a need". Requirements thus focus on understanding what kind of value could be delivered if a requirement is met. In this report, we distinguish between the following types of Requirements:

- **Business Requirements**, as high-level statements describing the overall goals of the project.

[1] See the project website at www.radioval.eu for the list of public deliverables.

- **Stakeholder Requirements**, defined as the needs of a particular group of stakeholders.
- **Regulatory Requirements**, defining needs and constraints from legislation and society.
- **Solution Requirements**, describing characteristic of the solution to be developed.

Clinical requirements are captured primarily in the project's Business Requirements and Stakeholder Requirements, while socio-ethical, legal, and regulatory requirements are a type of Regulatory Requirements.

Business Requirements are high-level statements that describe the goals and objectives of the business at the enterprise level. In a European R&I project like RadioVal, a diverse group of organisations temporarily joins forces to reach such a common set of goals. The goals of the project are laid out in a contract between the members of the consortium and the funding agency (the European Commission) – the Grant Agreement. This contract is the starting point for our requirements collection process. By analysing the Grant Agreement carefully, we have extracted a total of 44 Business Requirements. Not only are these an important input for the design of the RadioVal solutions; they essentially become the checklist for the project's overall success.

Next up, **Stakeholder Requirements** are extracted from the materials generated by the Social Innovation Sessions, patients' workshops, as well as 1-on-1 interviews that were held with various stakeholders in the project. From a group discussion between patients, healthcare professionals or other experts, it is not always immediately apparent what the actual needs of those stakeholders are. In this step, an interpretation of the discussions takes place, which is a potential source of error in defining requirements. We remedy this by carefully documenting for each Requirement: what was the Source, and what is the Author's Rationale behind their interpretation. These steps (tracking of Author, Source and Rationale) are also taken when defining Business Requirements but are much more crucial when interpreting spoken conversation in Stakeholder engagement sessions. A total of 158 Stakeholder Requirements were identified initially.

Regulatory Requirements are either high-level, or more detailed requirements that are derived from official regulatory documents. They describe, or more often refer to, applicable law. The project's legal experts have analysed the EU Medical Device Regulations (MDR), General Data Protection Regulation (GDPR) and the upcoming EU AI-Act and extracted a total of 15 requirements. This is a small number of requirements and indicates that the statements have been kept at a very high-level. This is adequate, since at the current phase of R&D that the RadioVal solution is in, it is likely not needed to focus on all the details. Those will become more relevant as the developed solution is entering into the pre-market stages.

After all these requirements have been defined, the Consortium went through a process of finding consensus on the clarity of these requirements. In multiple rounds of discussions between the project's requirements engineers, technical- and clinical partners, requirements have been rephrased, clarified, and in some cases rejected, leading to a final set of 184 requirements that are now being taken through the next steps.

Next steps

Each of the 184 requirements have been accepted as being clearly defined and as being something that would benefit the RadioVal solution if implemented. The next step is that of Prioritization. For this we use the commonly adopted MoSCoW-scheme[2] that classifies requirements as Must Have, Should Have, Could Have, or Won't Have, according to their priority for the specific context.

Finally, the next step in the process is an ongoing and continuous activity of translating Business Requirements, Stakeholder Requirements, and Regulatory Requirements into more detailed **Solution Requirements**. This is the creative and research-driven process of designing the RadioVal technological tools and the clinical processes for validating those tools – as such it is not a simple one-off step, but rather a

[2] https://en.wikipedia.org/wiki/MoSCoW_method

continuous process. Figure 1 below shows a schematic of the overall process that we have followed in eliciting requirements, and that we are following for deriving Solution Requirements and verifying and validating those.

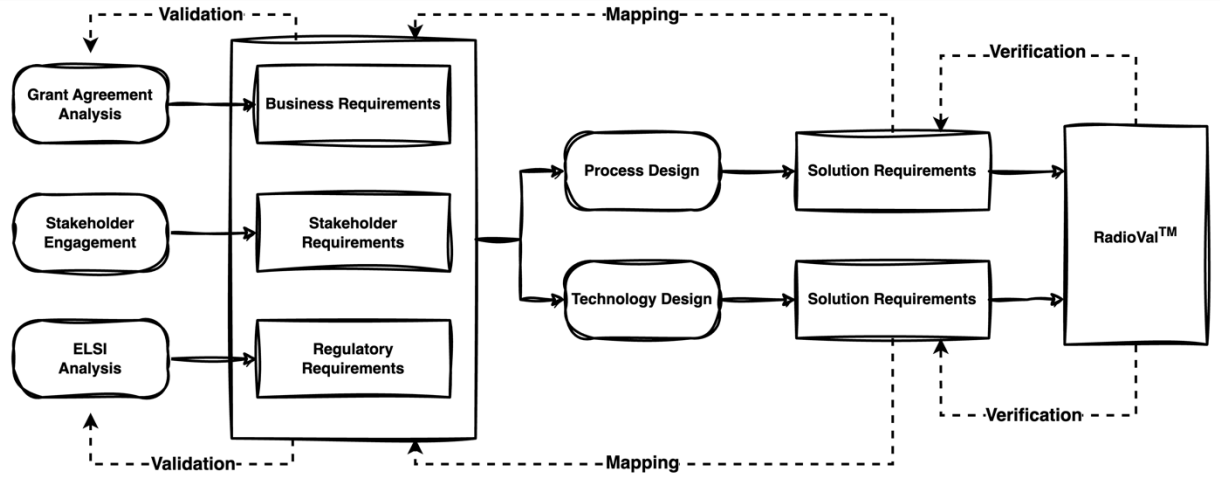

Figure 1: The requirements capturing and verification process in RadioVal.

From left to right, the process entails requirements elicitation as outlined above. The Grant Agreement leads to Business Requirements, Stakeholder Engagement activities lead to Stakeholder Requirements, and an ELSI analysis leads to Regulatory Requirements. Through Process Design and Technology Design, this input is translated into Solution Requirements. Solution Requirements describe what characteristics a particular solution will have to meet the needs of the stakeholders and business. They are often sub-divided in Functional- and Non-Functional Requirements, or into further subdivisions. In contrast to Business Requirements (which can be very high-level), and Stakeholder Requirements (which can describe wishes, needs or emotions), these Solution Requirements will be concrete, unambiguous, and verifiable statements that will directly lead to the technical designs and implementations of the RadioVal solution.

Finally, there are three processes that ensure correctness. From right to left in Figure 1, ***verification*** is the process of confirming that the developed solution matches its defined specifications (Solution Requirements). It answers the question: did we build what we set out to build? By ***mapping*** all Solution Requirements onto one or more Business-, Stakeholder-, or Regulatory Requirement, we can ensure that each of those latter requirements have indeed led to a specific element of the solution that addresses the requirement. It answers the question: where all our original requirements considered when defining solution requirements? And finally, ***validation*** is the process of confirming that the original requirements capture the needs of their stakeholders. As Business Requirements and Regulatory Requirements are generally not subject to interpretation, this process focuses on the Stakeholder Requirements, and aims to answer the questions: do our Stakeholder Requirements accurately capture what the stakeholders want.

Conclusion

We have defined an end-to-end process from engaging stakeholders all the way through delivering the RadioVal solution, that makes sure that information captured is not lost throughout the process as in a game of telephone[3]. A total of 44 Business Requirements, 158 Stakeholder Requirements, and 15 Regulatory Requirements were originally captured, leading to a final set of 184 requirements ready for prioritization and processing into solution requirements.

[3] https://en.wikipedia.org/wiki/Chinese_whispers