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A regulation-based project lifecycle for innovative medical devices: Delphi consensus from an Italian expert panel

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ABSTRACT

Background: The consideration and management of regulatory aspects within the lifecycle of medical device research projects in Public Research Institutions could facilitate translation to final users, but remains complex. Although the Medical Device Regulation (MDR) EU 2017/745 and related guidance define specific requirements, available tools and support structures are often oriented toward commercial manufacturers. Public Research Institutions may lack dedicated regulatory expertise and management processes. A practical gap therefore remains in translating regulatory requirements into phase-specific actions that can be integrated into academic research projects.

Objective: This work aimed to identify effective items to be considered throughout the lifecycle of research projects developing medical devices, in accordance with MDR EU 2017/745, to support adoption in practice of the resulting innovation.

Methods: A modified Delphi method was designed by a team of facilitators to collect/analyze suggestions from a selected panel of Italian experts with experience in medical device regulation and development. The team developed a questionnaire consisting of 46 questions organized according to key phases of a research project lifecycle: concept phase, research project design and plan, project execution and device development, project monitoring and control, and project closure.

Results: Twenty expert contributions were collected and harmonized. Thirty-three expert-derived statements were compiled, providing an overview of essential regulatory aspects to consider throughout the lifecycle of a medical device research project within Public Research Institutions.

Conclusions: This work may inspire effective practices and procedures to support a regulation-based approach for developing innovative medical devices in Public Research Institutions.

Public Interest Summary

Research institutions often develop promising health technologies, including medical devices. However, bringing these innovations into real-world use requires attention to regulatory requirements from the earliest stages of a project. This can be challenging in public research settings, where regulatory planning, dedicated expertise, and structured documentation practices may not be fully integrated into project management.

This study used a modified Delphi process involving Italian experts in medical device regulation and development to identify key regulatory aspects that should be considered during the lifecycle of a research project. The resulting approach follows the main project phases, from concept and planning to development, monitoring, and closure, and is aligned with the European Medical Device Regulation.

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By highlighting when/how regulatory issues should be addressed, this work might help Public Research Institutions improve governance, support smoother translation of research results into practice, and develop medical devices that can benefit patients, healthcare professionals, and society.

Background

The Medical Device Regulation (MDR) (EU) 2017/745 officially became fully applicable on May 26, 2021, and it is the primary legal framework governing the placing on the market and post-market surveillance of medical devices (MDs) in the European Union (EU). MDR overhauls the EU framework for MDs in response to concerns about patient safety, device performance and lifecycle transparency, raising standards of quality and safety while imposing a more demanding regulatory environment [1-5].

A headline reform is the broadened qualification/classification system, now more clearly covering technologies such as standalone software and mobile health apps. In particular, Rule 11 is a key MDR provision for the classification of medical device software, introducing a risk-based approach that explicitly links classification to the clinical impact of the information generated, particularly when used to support diagnostic or therapeutic decisions; its application has increased scrutiny of software supporting diagnostic or therapeutic decisions, often resulting in higher risk classifications, triggering more extensive clinical evidence and documentation requirements [2,3,5,6].

MDR mandates continuous clinical evaluation across a device's entire lifecycle, requiring manufacturers to provide robust premarket data and enhanced post market activities, such as real-world performance collection. To reinforce traceability, the Unique Device Identification system enables effective tracking and faster corrective actions [2]. While ensuring ongoing safety and effectiveness, these requirements add operational complexity [7,4].

The MDR has significantly expanded the oversight of notified bodies, requiring third-party reviews for a broader range of devices to ensure stricter safety standards. However, this increased scrutiny combined with a shortage of designated bodies and more rigorous certification requirements has led to market entry uncertainty and significant delays in device approval [6,8-11].

While MDR 2017/745 establishes higher safety and performance benchmarks, its inherent complexity is fundamentally reshaping the European MD's landscape. Successfully navigating this environment is critical for ensuring both the continued availability of safe devices and the sustained vitality of innovation within the EU healthcare system. To address these challenges, the Medical Device Coordination Group guidance on Breakthrough Devices ([12]–9) seeks to balance patient safety with the need for medical progress in treating life-threatening conditions. By clarifying how existing regulatory mechanisms apply to disruptive technologies, this guidance aims to secure robust clinical evidence while facilitating more timely access to transformative medical solutions. Public research institutions are pivotal in developing radically innovative medical devices, leveraging their position at the forefront of technology [13]. They prioritize scientific advancement and patient welfare over commercial gain, fostering interdisciplinary collaboration and open innovation to serve as essential catalysts for breakthrough discoveries and specialized spin-offs [14,15].

Publicly funded research drives conceptual innovation and early prototyping, while conducting essential usability and co-design studies to ensure clinical relevance [14,16-19].

Interestingly, integration of regulatory considerations early in research is perceived as relevant for translation but still too complex [20]. A significant gap exists because most regulatory frameworks and supports are tailored for commercial manufacturers, lacking the specific strategies needed to fit the structures of public research institutions [21-23].

A secondary gap involves the lack of dedicated regulatory departments and systematic training, which prevents researchers from accurately interpreting complex safety standards, risk management, and clinical validation [9,20,10]. Consequently, public research institutions often find the MDR's high evidentiary thresholds unattainable due to limited resources and fragmented expertise [24,22,23]. These challenges are further intensified by increasingly demanding and sometimes partially clarified regulatory leaving room for uncertainty for academic developers [25,26].

A third gap involves the limited availability of Quality Management Systems (QMS) aligned with ISO 13,485, leading to significant deficiencies in risk management and traceability within public institutions [21,27,23]. Furthermore, academic environments, typically focused on project-based research rather than long-term monitoring, struggle with continuous lifecycle documentation. This issue is intensified by academic reward systems that usually prioritize novel research over the regulatory maintenance and surveillance required for MDR compliance [28].

Lastly, academic institutions, deciding to assume the full responsibilities and liabilities of a legal manufacturer face a burden to be managed throughout specific know-how and structured procedures [23].

In Italy, Regulation (EU) 2017/745 is complemented at national level by Legislative Decree No. 137/2022 and subsequent ministerial decrees. In particular, clinical investigations require submission to the Ministry of Health and must be accompanied by the opinion of the competent National or Territorial Ethics Committee. Innovators should also anticipate the evidentiary standards later applied by Notified Bodies during conformity assessment, as clinical evaluation planning and implementation reporting under MDR Annex XV will feed into future certification and market-entry pathways together with technical documentation. For public research institutions, this process can be challenging since it requires regulatory expertise and organizational structures that are not always systematically available in academic settings.

Despite promising examples of integrated regulatory strategies [29, 30] and consensus initiatives – e.g. the 3D Innovation Lab at Humanitas and Politecnico di Milano [31] and the 1st EFORT European Consensus [32] – the suitability of a regulatory framework for both private and public developers remains an open issue. Without transversal mindset and adapted pathways, the MDR may inadvertently slow the translation of academic innovations into clinical practice [22,23] and create an elevated risk of non-compliance [6,9-11].

To effectively comply with the MDR and ensure timely patient access to innovation, public research organizations require enhanced access to regulatory expertise, targeted training, and dedicated institutional support [33,23].

Further research is required to identify effective mechanisms for enabling public research institutions to navigate regulatory and organizational barriers [34]. This study focuses on how to facilitate the integrated consideration and management of regulatory aspects within academic settings. The objective is to provide public-sector innovators with a comprehensive overview of key MDR EU 2017/745 considerations across the entire project lifecycle, aimed at developing a MD, to enable the successful translation into clinical practice.

Methods

A modified Delphi method [35-37] was applied by a team of facilitators in order to collect and analyze suggestions from a group of experts from Italy for the application of a regulatory mindset within innovative research projects aimed to develop medical devices. The main addressed target for the final output included public research institutions, both in terms of institutional representatives and operative involved personnel.

More specifically, eight facilitators from the Italian National

Research Council, Pisa and Florence Universities discussed and identified the activities that, from the regulatory perspective, can be integrated within the lifecycle of a research project (Fig. 1).

The harmonized consideration and management of regulatory aspects during the phases outlined in Fig. 1 could be useful for speeding up the translational process of innovative technologies, but it is often critical for research institutions [20]. Within this context, the facilitators identified this key initial question: "**how can the consideration and management of regulatory requirements within Research Entities developing innovative medical devices be facilitated?**" and articulated it into more detailed subgroups of questions following the specific phases outlined in Fig. 1. A separate formal pilot test with an independent panel was not conducted. Before administration, this first-round questionnaire was reviewed and validated by two external members for clarity, relevance, and completeness, and minor revisions were introduced. During this review, these external members were specifically consulted regarding the time required to complete the questionnaire, confirming that the expected commitment was acceptable. The questionnaire was then administered via e-mail to a panel of selected experts to gather their feedback. After this first round, the responses were analyzed and summarized for each phase. The resulting items were then sent to the experts to reach a shared agreement based on a 5 Likert scoring. More details are reported in the subsequent paragraphs.

Expert panel composition

The Delphi panel consisted of Italian professionals with extensive experience and direct involvement in activities pertinent to medical device development. The primary target audience for this consensus process was mainly, but not exclusively, based on the consortium of THE (Tuscany Health Ecosystem – www.tuscanyhealthecosystem.it) including researchers engaged in innovative medical devices, regulatory experts, life sciences business development managers, representatives from clinical trials and knowledge transfer offices, ethics committees and a notified body. THE was used as a pragmatic starting network because it includes multiple actors directly involved in public research-driven medical device innovation. To broaden professional perspectives, the panel was not limited to consortium members and additional experts were invited on the basis of their role and experience in medical device development and regulation in Italy. Experts were purposively identified on the basis of direct experience with medical device development covering different aspects of the pipeline and providing complementary backgrounds. Twenty-five experts were invited by email in March 2025 introducing the scientific initiative and background, and twenty agreed to participate. The mean professional experience in the medical device field was 14 ± 6.5 years.

Delphi procedure and rounds

The consensus process followed a modified Delphi method conducted remotely over iterative rounds of structured questionnaires. The study was defined as a modified Delphi mainly because the initial domains were not generated entirely de novo by the panel. The facilitators established a predefined research project lifecycle model to structure the first-round questionnaire. Experts' input was then used to refine and populate this framework.

In particular, the first round (Round 1) included a questionnaire with 46 open questions organized according to the identified phases of the research project lifecycle (*see supplement material - survey 1*).

The open responses from Round 1 were analyzed by the facilitator team through a directed content analysis approach [38], a structured procedure guided by the predefined project lifecycle phases. The facilitators extracted relevant meaning units from each response and mapped them to the corresponding lifecycle phase and question. Overlapping or conceptually similar inputs were grouped, while comments expressing uncertainty, disagreement, or conditional applicability were specifically retained to ensure a comprehensive overview. The resulting synthesis was then transformed into a set of harmonized candidate items that was then submitted to the experts for scoring in Round 2. Because the analytical categories were established a priori by the lifecycle framework, this procedure was not an inductive thematic analysis; rather, it was a facilitator-led structured synthesis aimed at generating consensus statements.

This output was shared with the experts asking for their feedback for each item based on a 5 Likert scoring, with 1 representing the worst level of agreement, (*see supplement material - survey 2*) and with the possibility of providing comments. A 5-point Likert scale was selected to reduce respondent burden in a relatively long survey and to facilitate clear interpretation of disagreement (1–2), neutrality (3), and agreement (4–5). Although 7- or 9-point scales may capture finer gradations of opinion, the 5-point format was considered appropriate for assessing relevance and endorsement of operational statements. Each round was administered electronically. Feedback between rounds was provided only in aggregated form. The process was blinded: experts knew only who the facilitators were, not who the other experts involved in the initiative were, and they did not interact with one another during the rounds. The Delphi process was conducted from March 2025 to December 2025 as summarized in Fig. 2. The interval between rounds was approximately three months, allowing sufficient time for reflection and potential adjustment of opinions. Then, the facilitators derived from

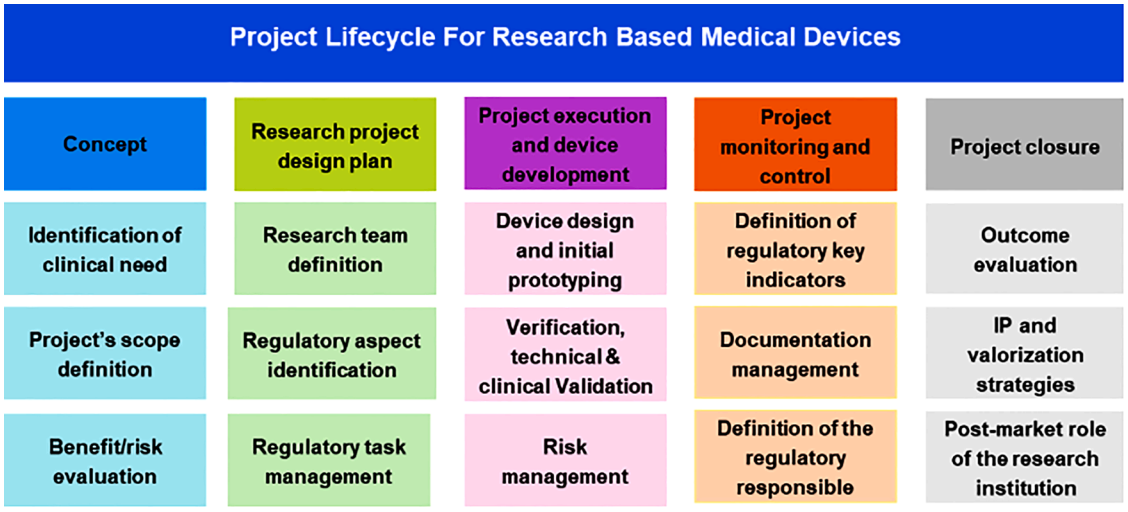

Fig. 1. – Research project lifecycle for medical device development process.

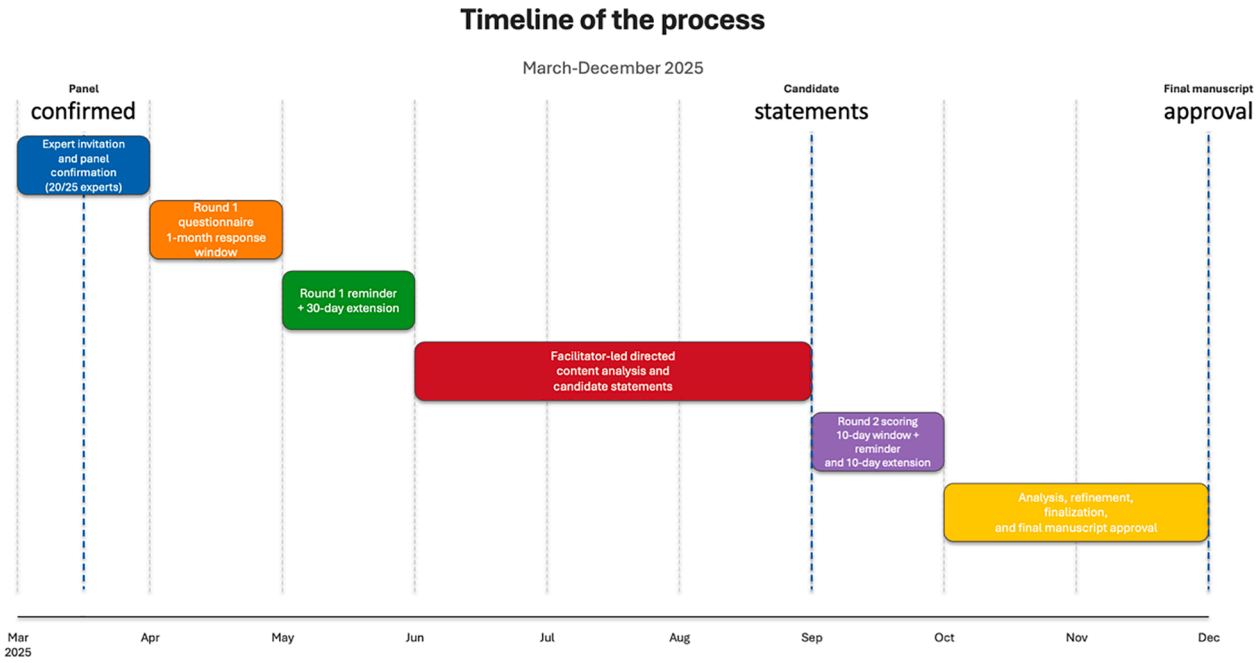

Fig. 2. – Delphi process timeline: from expert invitation to final manuscript approval. Experts were initially contacted in March 2025. After confirmation of participation by 20 of the 25 invited experts, the first-round questionnaire was administered electronically and asynchronously. To manage the burden associated with 46 open questions, the questionnaire was organized into lifecycle phases. Experts were allowed sufficient time for completion, with an initial one-month response window for Round 1 and a ten-day response window for Round 2. During Round 1, a single reminder was sent to non-respondents, granting a 30-day extension. The facilitator-led directed content analysis of Round 1 responses then required approximately three months to synthesize the qualitative inputs into candidate statements. In Round 2, experts scored the harmonized items and could provide comments where clarification or disagreement was needed. A subsequent reminder was issued to those who had not yet completed the questionnaire, providing an additional 10 days; this shorter extension reflected the more focused nature and faster completion of the second-round scoring task. The subsequent analysis, refinement, finalization of the consensus set, and approval of the final manuscript were completed over approximately two months. Overall, the process, from expert invitation to final manuscript approval, was completed by December 2025.

these steps a final list of expert-derived statements and approval was obtained. All twenty experts completed Round 1 and Round 2, and all participated in the final review and approval step.

Consensus definition and thresholds

Consensus on the items was defined as follows: i) a median score ≥ 4 (on a 5-point Likert scale) was considered indicative of agreement that the item was relevant and endorsed by the panel; ii) in addition, a disagreement rate $\leq 10\%$ (i.e., proportion of scores ≤ 2) was required for consensus to be confirmed. Items meeting both criteria were classified as having achieved consensus. Qualitative comments were analysed and reported if considered relevant by the facilitators.

Handling of dissent

In case of items not meeting the consensus thresholds, the planned approach included a re-evaluation in subsequent further Delphi rounds and a qualitative analysis of persistent dissent to identify the sources of disagreement. The process was intended to continue until either the predefined consensus thresholds were reached or response stability was observed across rounds. Stability would have been assessed by examining changes in the coefficient of variation, while overall panel concordance would have been evaluated using Kendall's W.

Results

As reported in the methods section, three Delphi steps were implemented: collection of open expert contributions, scoring of facilitator-derived items, and final review and approval of the resulting statements. In the first one twenty contributions from the expert panel were collected and harmonised by the team of facilitators. Within a second consultation, the items obtained by the facilitators from the experts' answers received a strong level of agreement with median values ranging from 4 to 5 on a 5-point Likert scale (*see supplemental material-survey 2*). These two steps were sufficient to define the items and reach the predefined thresholds, without need of dissent handling. Because all items met the predefined thresholds, no additional scoring round and no formal statistical stability analysis were performed. In fact, the experts reported an overall disagreement rate of 1.2%, which never surpassed 10% when expressed on a single item. The few instances where some experts gave a score of '2′ (classified as disagreement) were all strongly justified. These motivated disagreements were addressed, integrated into the text, and subjected to a final third review step, resulting in a global agreement. Similarly, scores of '3′ (neither agree nor disagree) that were accompanied by comments were also consistently integrated. Finally, the facilitators combined those items providing similar or overlapping indications. In the end, thirty-three expert-derived statements were obtained and approved: these are reported in Table 1, offering a comprehensive overview of the essential regulatory MDR aspects to be considered throughout the lifecycle of a research project conducted in Public Research Institutions and aimed to develop a medical device.

The emerged comments between rounds are summarized below. In general, the project's specific reference context emerged as a relevant element across different phases of the questionnaires, with emphasis on innovative medical technologies, and on the necessity for considering regulatory issues, supported by a high-level vision within the Research Institute.

0- CONCEPT.

Some experts commented that a thorough assessment of the state of the art and a preliminary benefit-risk evaluation is recommended. The

Table 1
Expert-derived statements - regulatory aspects under EU MDR 2017/745 throughout the entire lifecycle of a research project within public research institutions developing medical innovations intended for clinical use .

0-CONCEPT
a. Regulatory accountability in academia and industry should consider compliance with Medical Devices Regulation (MDR), In Vitro Diagnostic Regulation (IVDR), and Good Clinical Practice (GCP), but may differ in structure, goals, and mechanisms since academia focuses on early-stage research and societal benefit, while industry manages broader stakeholder demands, formalized systems, and post-market responsibilities.
b. A research project aimed at developing and translating into practice new medical devices should consider improvement in clinical outcomes or reduce risks through ethically sound, evidence-based innovation, with early integration of regulatory, technical, and user-related considerations to ensure feasibility, impact, and translational success.
c. An early integration of regulatory planning in research - through e.g. Regulatory Intelligence, access to standards, and expert support - ensures feasibility, guides design, and aligns innovation with compliance, especially as projects advance toward technology readiness.
1-RESEARCH PROJECT DESIGN AND PLAN .
a. The Principal Investigator should ensure that a regulatory perspective is considered.
b. To facilitate clinical translation, the planned research team could benefit from internal or external regulatory expertise.
c. Specific regulatory aspects that should be considered in the plan are, at least, intended use, qualification and preliminary classification.
d. A dedicated regulatory work package, when possible, is recommended.
e. Within this and the subsequent phases, the innovators can use some support sources available for free (tables 2 and 3).
2-PROJECT EXECUTION AND DEVICE DEVELOPMENT: TECHNICAL AND PRE-CLINICAL TESTING
2.1-DEVICE DESIGN AND INITIAL PROTOTYPING
a. Regulatory evidence of feasibility can be provided through a combination of design documentation, proof-of-concept prototypes, and feasibility studies.
b. A preliminary analysis of general safety and performance requirements (GSPR, Annex 1) can be started early in the design and development process, once the intended use and device concept are defined.
c. Fragmentation of data and documentation useful for the regulatory strategy can be avoided with a standardized approach to documentation and tracing of design inputs, outputs, verification methods, and results.
2.2-V&V&V (VERIFICATION, TECHNICAL VALIDATION, CLINICAL VALIDATION)
2.2.1-Technical reliability and biocompatibility
a. For technical verification, the team should consider demonstration that the device meets its design specifications and intended use in alignment with the General Safety and Performance Requirements (GSPR).
b. When appropriate depending on the kind of device, the team should include the evaluation of precision, accuracy, usability, and reliability of the device in the technical validation process.
c. When appropriate depending on the kind of device, key elements to define the technical, biocompatibility, and biological safety tests needed for preclinical testing are material compositions, interaction type, and duration with patient tissues, including device specification and risk analysis.
d. Specific safety tests should be carried out in laboratories that meet quality requirements (e.g., adherence to validated protocols, international standards, qualified personnel, and full documentation).
2.2.2- Preclinical models
a. Researchers should follow GLP principles on animal model selection and refer to 3Rs principles and guidelines like ARRIVE.
b. Researchers should ensure that any computational models used to support safety and performance are scientifically validated, transparently documented, and aligned with clinical or experimental evidence, as required by MDR Annex II and GSPR 10(e).
c. Researchers could consider scientifically validated alternative models - such as 3D cultures, organoids, and organ-on-chip systems - to complement or partially replace animal testing, provided that these models are accepted to ensure the resulting data can be used to support regulatory evidence.
2.2.3- Clinical evaluation
a. Principal Investigator, supported by specific clinical expertise in the team, is responsible for starting the clinical evaluation process.
b. Relevant clinical data on equivalent or similar medical devices might be initially sourced from peer-reviewed literature, clinical guidelines, safety notices, public databases, and third-party registries like MAUDE or EUDAMED.
c. To initiate an effective clinical evaluation, the team should be open to interactions with external stakeholders (such as Ethics Committees, health authorities, etc.).
d. In line with Articles 62–82 of the MDR and supporting guidance, clinical investigation strategies could follow a phased, risk-based approach. This could e.g., begin with early exploratory studies under Article 82 - such as pilot and first-in-human (FIH) studies - and progress to pivotal investigations under Article 62.
e. The development team should support the creation of understandable and objective Investigator Brochure (IB).
2.2.4- Risk management
a.Risk assessment and management should be initiated at the earliest stages of the research project by the Principal Investigator in close coordination with the team, ideally during conceptualization, and should be maintained dynamically throughout the entire device lifecycle with subsequent involvement of other stakeholders.
b. Traceability of risks, mitigation actions, design requirements, and verification tests should be systematically implemented from the design phase throughout the project lifecycle.
3- PROJECT MONITORING AND CONTROL
a. Key Performance Indicators (KPIs) can be considered for monitoring the regulatory evolution and overall performance, particularly: timeliness and regulatory progress, audit and inspection readiness, documentation and data management, milestone and deliverable achievement, product performance and risk management.
b. Regulatory aspects management could be monitored within the project Gantt chart. Integration with visual project management tools enhances task assignment, document sharing, and team coordination. Additional tools include dashboards, regulatory checklists, document control systems, compliance software, and internal audits. A well-defined Design Validation Plan is valuable, detailing tests, sample sizes, and sequencing - especially for time-sensitive processes like sterility assurance.
c. A dedicated, trained regulatory figure or unit - similar to a PRRC ((Person Responsible for Regulatory Compliance) - is desirable to oversee regulatory compliance throughout the project lifecycle supporting the PI and team within research institutions.
4- PROJECT CLOSURE
a. The outcome of a research project can be valued from a regulatory perspective, particularly when it aims at clinical application, certification, or market readiness.
b. To demonstrate a robust regulatory strategy during a research project, the involved Research Institution or spin-off could prepare a preliminary but structured Medical Device File.
c. Negotiations between research institutions and industry for the valorization of medical device innovations should occur after Intellectual Property (IP) protection, and once initial regulatory strategy has been identified and technical milestones have been achieved.
d. The most compelling regulatory elements for industry include a clear and realistic roadmap, early evidence of safety and performance, documentation supporting manufacturability and quality management.
e.The finalization of regulatory pathways for research-derived innovations requires targeted financial incentives, early regulatory engagement, and institutional support mechanisms.

initial spark of innovation can be fueled by curiosity-driven research, keeping the project's scope aimed to identify advancements in terms of either clinical benefit or risk reduction, possibly stemming from an unmet clinical/health need. Crucial information sources include scientific literature and medical guidelines (to assess evidence and safety parameters), market analysis and patents, and the experience of healthcare professionals.

1- RESEARCH PROJECT DESIGN AND PLAN.

It was highlighted that, during this phase, interaction with regulators could be useful and should be mediated by experts (e.g., academic, consultants) to identify and address specifically possible grey areas needing clarification.

2- PROJECT EXECUTION AND DEVICE DEVELOPMENT: TECHNICAL AND PRE-CLINICAL TESTING.

The experts underlined that this phase is highly dependent on the type of technology; moreover, it was underlined that EU MDR 2017/745, device-specific MDCG guidance, and standards should be followed, and that it would be important making ISO and product-specific standards easily accessible for the research institutions. The consideration of scientifically validated alternative models, such as 3D cultures, organoids, and organ-on-chip systems, used to complement or partially replace animal testing, was perceived as possible with some contributions highlighting that the results obtained from these techniques may not be recognized in the certification process since there are no guidelines from regulatory authorities yet.

Relevant clinical data on equivalent/similar medical devices, which must encompass clinical, biological, and technical data (including design and performance requirements), can be sourced from peer-reviewed literature, clinical guidelines, safety notices, public databases, and third-party registries (like MAUDE or EUDAMED, when available). However, experts evidenced that also in research project demonstrating equivalence is complex because it requires up-to-date information on already marketed devices, which can be difficult to be obtained and might require direct agreement with the manufacturer.

Regarding the clinical evaluation phase, the Principal Investigator of the project, supported by specific clinical expertise within the team, is considered directly responsible for managing the initial clinical evaluation process. Within this activity a combination of EU regulations, international standards, national laws, and guidance documents, tailored to the specific device and study context, should be consulted. Research institutions may take on various roles in a clinical investigation, when this is needed: they can act as sponsors, host institutions for principal investigators, or even as legal manufacturers, depending on their level of involvement.

3- PROJECT MONITORING AND CONTROL.

For this phase, no specific additional qualitative free-text comments requiring narrative discussion were provided.

4- PROJECT CLOSURE.

The development of a preliminary but structured Medical Device File is perceived as an opportunity for the involved Research Institution or spin-off. The experts highlighted that while the technical documentation serves as the evidence base required by a Notified Body to ultimately obtain the CE marking and it is unlikely to be fully achievable in the early stage of a device development, an early and structured preparation of this documentation represents the most effective way to demonstrate and execute a robust regulatory strategy.

Regarding the role of a research institution in post-market activities, the experts agreed that it depends primarily on whether the institution acts as the legal manufacturer. Furthermore, post-market studies may also be non-profit in nature, i.e., promoted by research entities that are not the manufacturers of the medical device. Even in these cases, the research institutions can be involved in the Post-Market Surveillance (PMS) process by providing valuable feedback on how the device performs in real-world settings. They should also report any safety concerns to the appropriate regulatory body.

Across all project phases, specific questions were structured to elicit from the experts some key normative references applicable to each phase of medical device design and development projects, alongside recommended available regulatory support sources. These generated references and sources could aim to further facilitate a comprehensive consideration of regulatory aspects throughout the various project stages. Accordingly, Tables 2 and 3 detail the suggested Phase-Specific Normative References and Free Regulatory Support Sources, respectively.

Discussion

This study provides a concrete and operational response to the regulatory complexity highlighted in the literature. While MDR 2017/745 has introduced significantly requirements for safety, performance, traceability, and post-market surveillance [2,3-5], the expert-derived statements demonstrate how these principles could be systematically operationalized within the specific organizational and cultural approach of Public Research Institutions. From a theoretical perspective, this study contributes to the current literature by complementing existing descriptive analyses of MDR-related barriers in public research [21,10,23] with a lifecycle-based interpretation of regulatory integration as a relevant dimension of translational research governance.

The high level of consensus achieved across the derived regulatory items confirms that, despite the different missions and conditions of academic research and the private sector [20], the consideration of regulatory complexity is widely acknowledged. Furthermore, the findings suggest that shared expert knowledge could effectively facilitate it through a practicable operational model. The provided information, about the Phase-Specific Normative References and the Free Regulatory Support Sources, further sustain the adoption of such approach.

At the earliest stages of innovation, the strong emphasis on benefit–risk assessment, state-of-the-art analysis, and the identification of unmet clinical needs directly responds to the MDR focus on clinical evaluation and safety from the earliest stages of development [7,2] and theoretically reinforces the notion that regulatory reasoning should be considered as an intrinsic dimension of scientific design rather than a downstream constraint. This finding addresses the previously reported difficulty of integrating regulatory inputs during early academic research, where such aspects are often perceived as relevant but excessively complex [20], and contributes to reframing regulatory planning as a best practice in MD innovation.

Early, expert-mediated engagement with regulators and the inclusion of regulatory expertise in project design align with the evolving interpretation of MDR requirements [25,26], and improve the related capacity of academic environments [9,20,10]. From a practical standpoint, this translates into actionable organizational solutions – such as dedicated regulatory work packages – that directly mitigate the structural mismatch between industry-oriented regulatory frameworks and the exploratory, project-based nature of academic research [21-23].

During project execution and device development, the detailed guidance on General Safety and Performance Requirements (GSPR, MDR Annex I) analysis, verification and validation, documentation standardization, risk management, and clinical evaluation provides the necessary operational basis to consider the major obstacles related to MDR requirements for highly innovative academic technologies [24,22,23]. At a theoretical level, these findings reinforce the concept of regulatory evidence generation as a continuous learning process rather than a single certification milestone, while at a practical level they provide concrete tools to overcome the documented deficiencies in QMSs and traceability procedures within Public Research Institutions [21,27,23]. The experts' caution regarding the limited regulatory recognition of alternative preclinical models such as organoids and organ-on-chip systems further confirms the persistent misalignment between scientific innovation and current certification pathways [25,26], highlighting a systemic issue that extends beyond individual institutional efforts and calls for regulatory evolution at policy level.

The structured attention devoted to project monitoring, specific regulatory Key Performance Indicators (KPIs), and continuous oversight reflects the relevance of MDR's requirement for sustained lifecycle approach [2,4] while directly addressing the public research difficulty in maintaining long-term documentation and regulatory engagement within traditionally short-term project-based research planning [28]. The recommendation for a trained regulatory personnel or unit within

Table 2
– Indicative phase-specific normative references.

Project phase	Norm		Description	Link
Device design and initial prototyping	EU MDR 2017/745, Medical Devices Regulation, https://eur-lex.europa.eu/eli/reg/2017/745/oj	ISO 13,485	Medical devices - Quality management systems - Requirements for regulatory purposes	https://www.iso.org/standard/59752.html
	MDCG guidance, Medical Device Coordination Group, https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en	ISO 14,971	Medical devices - Application of risk management to medical devices	https://www.iso.org/standard/72704.html
		GCP - ICH E6 R3	Good Clinical Practice	https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
		GDPR	General Data Protection Regulation	https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng
		AI Act	Artificial Intelligence Act	https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng
		IVDR (2017/746)	In vitro diagnostic medical devices and repealing Directive	https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng
V&V&V (verification, technical validation, clinical validation)- Technical reliability and biocompatibility		ISO 13,485	Medical devices - Quality management systems - Requirements for regulatory purposes	https://www.iso.org/standard/59752.html
		ISO 14,971	Medical devices - Application of risk management to medical devices	https://www.iso.org/standard/72704.html
		ISO 10,993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	https://www.iso.org/standard/68936.html
		ISO 10,993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process	https://www.iso.org/standard/64750.html
		ISO 10,993-17	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents	https://www.iso.org/standard/75323.html
		IEC 60,601	Medical electrical equipment	https://www.iso.org/standard/65529.html
		IEC 62,304	Medical device software - Software life cycle processes	https://www.iso.org/standard/38421.html
V&V&V (verification, technical validation, clinical validation)- Preclinical models		GLP	Good Laboratory Practice principles	https://www.oecd.org/en/publications/revised-guides-for-compliance-monitoring-procedures-for-good-laboratory-practice_9789264078550-en.html
		The 3Rs principles	Replacement, Refinement and Reduction of animals in research	https://nc3rs.org.uk/who-we-are/3rs
		ARRIVE guidelines	Animal Research: Reporting of In Vivo Experiments guidelines	https://arriveguidelines.org/
		ISO 14,630	non active surgical implants	
		ISO 10,993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	https://www.iso.org/standard/68936.html
		ISO 14,971	Medical devices - Application of risk management to medical devices	https://www.iso.org/standard/72704.html
V&V&V (verification, technical validation, clinical validation)- Clinical evaluation		IVDR (2017/746)	In vitro diagnostic medical devices and repealing Directive	https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng
		GDPR	General Data Protection Regulation	https://eur-lex.europa.eu/eli/reg/2016/679/oj/eng
		ISO 14,155	Clinical investigation of medical devices for human subjects - Good clinical practice	https://www.iso.org/standard/71690.html
		GCP - ICH E6 R3	Good Clinical Practice	https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
		ISO 14,971	Medical devices - Application of risk management to medical devices	https://www.iso.org/standard/72704.html
		WMA Declaration of Helsinki	Ethical principles for medical research involving human participants	https://www.wma.net/policies-post/wma-declaration-of-helsinki/
		DL 137/2022	Italian national legislative decree for the alignment of national legislation with the MDR	https://www.gazzettaufficiale.it/eli/id/2022/09/13/22G00145/sg
		DL 211/2003	Italian national legislative decree establishing provisions concerning the conduct of clinical trials	https://www.gazzettaufficiale.it/eli/id/2003/08/09/003G0229/sg
		DM 12/04/2023	Italian Ministerial Decree on the submission of communications related to clinical investigations for CE-	https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2023–06–13&atto.codiceReda

(*continued on next page*)

Table 2 (*continued*)

Project phase	Norm		Description	Link
			marked devices used within their intended purpose	zionale=23A03357&elenco30giorni=false
		MEDDEV guidance	Medical Devices Directives	https://health.ec.europa.eu/document/download/c1a6aa0b-d8c8-498b-8ed4-9f3c6211896d_en
V&V&V (verification, technical validation, clinical validation)- Risk management		ISO 14,971	Medical devices - Application of risk management to medical devices	https://www.iso.org/standard/72704.html
		ISO/TR 24,971	Medical devices - Guidance on the application of ISO 14,971	https://www.iso.org/standard/74437.html
		EU MDR 2017/745	Medical Devices Regulation	https://eur-lex.europa.eu/eli/reg/2017/745/oj
		IEC 62,366-1	Medical devices - Part 1: Application of usability engineering to medical devices	https://www.iso.org/standard/63179.html
		IEC 62,304	Medical device software - Software life cycle processes	https://www.iso.org/standard/38421.html
		AAMI TIR32	Medical device software risk management	
		IEC TR 80,002-1	Medical device software	https://www.iso.org/standard/54146.html
		NIST AI Risk Management Framework	Specific technology based on Artificial Intelligence	https://www.nist.gov/itl/ai-risk-management-framework
		ISO/IEC 23,894	Information technology - Artificial intelligence - Guidance on risk management	https://www.iso.org/standard/77304.html
		ISO 13,485	Medical devices - Quality management systems - Requirements for regulatory purposes	https://www.iso.org/standard/59752.html
		ISO 14,155	Clinical investigation of medical devices for human subjects - Good clinical practice	https://www.iso.org/standard/71690.html
		MDCG 2024–3	Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices	https://health.ec.europa.eu/document/download/690de85a-ac17-45ea-bb32-7839540c25c4_en?filename=mdcg_2024-3_en_0.pdf
		IMDRF guidelines	Guidance on the implementation and integration of a risk management system within a medical device manufacturer's quality management system.	https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n15r8-risk-management-principles-qms-050520.pdf
Project monitoring and closure		ISO 13,485	Medical devices - Quality management systems - Requirements for regulatory purposes	https://www.iso.org/standard/59752.html

Public Research Institutions represents both a theoretical shift toward institutionalizing regulatory competence as an organizational capability and a practical solution to the widely reported lack of internal regulatory capacity [20,10].

Finally, the clarification of institutional roles in post-market surveillance responds directly to the legal, administrative, and liability burdens faced by Public Research Institutions when assuming the role of legal manufacturer [21,23]. These findings strengthen existing theoretical arguments on the importance of early integration of regulatory considerations for translational success [29,30] and offer a pragmatic pathway to reduce the elevated risk of non-compliance associated with late regulatory engagement [9,31,10].

Overall, this study offers a dual contribution by framing regulatory integration as a transversal, lifecycle-oriented dimension of MD innovation in public research, and by providing a phase-specific, expert-validated approach that is directly applicable within Public Research Institutions.

MDR complexity remains a systemic challenge, the proposed approach delivers a concrete mechanism to reduce regulatory uncertainty, organizational fragmentation, and evidentiary gaps that continue to hinder the clinical translation of publicly developed innovations [34,22,23]. In this sense, this work represents a tangible step toward enabling Public Research Institutions to operate more effectively within the demanding MDR environment, while preserving their core mission of curiosity driven and independent innovation and patient-centred technological advancement. It is worth noting that regulatory readiness should not be interpreted as sufficient, by itself, to ensure clinical translation. For research-derived medical technologies, early attention should also be given to other relevant aspects such as health economic evaluation, reimbursement pathways, procurement requirements, market access, and adoption by healthcare professionals and organizations. Early health technology assessment can help clarify value drivers, evidence needs, uncertainty, and potential barriers to reimbursement and diffusion. The regulatory lifecycle approach proposed here should be viewed as complementary to early value assessment and market-access planning [40,41].

Since the MDR is a directly applicable regulation across all in EU Member States, the core technical principles identified by the Italian panel - such as early definition of intended use, preliminary qualification/classification, GSPR mapping, risk management, verification and validation planning, clinical evaluation, and lifecycle documentation - are conceptually relevant within the European regulatory space. Nevertheless, practical implementation may differ substantially across Member States. Variations in the organization of Ethics Committees, specific Competent Authority workflows and national reimbursement pathways mean that while the requirements remain the same across the EU, the managerial steps may differ. For international contexts outside the EU, the proposed lifecycle logic may still be useful as a project-governance model for medical device development, but the specific regulatory references and procedural steps would need to be replaced by

Table 3
Free Regulatory Support Sources.

	name	link
European Commission and MDCG Resources	European Commission's Medical Devices Sector	https://health.ec.europa.eu/medical-devices-sector_en
	Medical Device Coordination Group (MDCG) guidance portal	https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en
	EUDAMED - European Database on Medical Devices	https://ec.europa.eu/tools/eudamed/#/screen/home
Other Institutional and Governmental Resources	EMA Innovation Task Force	https://www.ema.europa.eu/en/human-regulatory-overview/research-development/supporting-innovation
	AIFA Innovation Meeting	https://www.aifa.gov.it/en/innovazione-e-scientific-advice
	FDA 513(g) Requests Program	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic
	FDA Safer Technologies Program	https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-medical-devices
	FDA Breakthrough Devices Program	https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program
Multilateral and International Guidelines	IMDRF (International Medical Device Regulators Forum) guidance	https://www.imdrf.org
	WHO (World Health Organization)	https://www.who.int/health-topics/medical-devices#tab=tab_1
	European Association of Notified Body	https://www.team-nb.org/team-nb-documents/
	ISO guidelines	https://www.iso.org/standards.html
Open Platforms	UBORA	https://ubora-biomedical.org/
	Medical device development tools (MDDT)	https://www.fda.gov/medical-devices/medical-device-development-tools-mddt
	QDC GmbH MDR-MDCG tool	https://www.eu-lex.qdc-beratung.ch/
Online webinars, papers, and forums	Greenlight Guru	https://www.greenlight.guru/
	MedTech Europe white paper	https://www.medtecheurope.org/
	Atlassian forums	https://community.atlassian.com/
	Open-access scientific publications – statistical framework for digital medical devices evaluation	https://doi.org/10.1002/sim.70572 [39]

the applicable national or regional requirements.

Limitations

A major limitation of this study is the geographical and institutional context of the expert panel. Although the MDR is directly applicable across the EU, the experts were Italian and were primarily, although not exclusively, connected to the Tuscany Health Ecosystem. The findings should therefore be interpreted as an expert-informed framework developed in this Italian public research context rather than as a fully representative international consensus. Transferability to other countries, regions, or institutional environments requires consideration of different aspects like national competent-authority procedures, ethics committee structures, reimbursement systems, and the availability of institutional regulatory-support units. A further limitation is that the questionnaire and candidate statements were facilitator-led and based on a predefined lifecycle framework. Although this approach is consistent with a modified Delphi design, it may have influenced the consensus process and limited the emergence of alternative perspectives.

Conclusions

This study represents an initial effort to structure and promote a regulation-based approach to the development of innovative MDs within Public Research Institutions. It shows that, despite the heightened regulatory complexity introduced by MDR 2017/745 and the structural constraints affecting Public Research Institutions, the systematic integration of regulatory considerations across the entire research and development lifecycle is both feasible and necessary within academic settings. By translating regulatory requirements into thirty-three phase-specific, expert-validated statements, the proposed approach offers a structured and practicable operational tool that directly addresses key gaps identified in the literature. At the same time, it is designed to support the concrete, day-to-day research and development activities of Public Research Institutions engaged in the mission of translation of innovative MDs into clinical practice.

The strong level of expert consensus supports the robustness and practical relevance of the proposed guidance. However, this study did not directly measure downstream outcomes related to translation of public medical research innovations, such as successful certification, implementation in clinical practice, or patient access, that should be evaluated in future studies.

Although this work represents an initial effort and is limited by the regional scope of the expert involved – who are primarily based in the Tuscany region, as the research was conducted within the framework of the Tuscany Health Ecosystem project – its methodological approach and outcomes appear potentially transferable to broader institutional and technological contexts. Overall, reinforcing regulatory awareness, expertise, and dedicated institutional support within public research environments emerges as essential not just to ensure MDR compliance but also to preserve innovation capacity and promote the possibility of timely patient access to safe and effective MDs.

Prospective research should test this lifecycle-based regulatory approach in live medical device research projects. Pilot implementation could assess feasibility, acceptability, required resources, documentation completeness, timeliness of regulatory milestones, quality of risk-management and GSPR mapping, and the usefulness of regulatory KPIs. Further studies should validate the framework across EU Member States, evaluate its adaptation in non-EU regulatory environments, and assess whether early regulatory planning combined with health economic, reimbursement, and market-access assessment improves translational readiness and decision-making. More generally, future research could empirically validate the application of this approach in diverse settings and explore policy-level mechanisms to further facilitate osmosis of regulatory systems with the specific mission and constraints of public research innovation. In addition, if adopted at scale, assessing its impact in terms of cost-effectiveness could provide valuable evidence on its economic sustainability and broader health-system value.

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Conflict of interest statement

EB is co-founder of QUIPU s.r.l., Pisa, Italy, a spin-off company of the

Italian National Research Council and the University of Pisa developing software as a medical device.

AR is founder of InsideAI, a company supporting the development of innovative AI based solution in the medical field.

GV received honoraria from Baxter spa; GV is founder of Hemathica srl.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.hlpt.2026.101248.

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