MedTech Europe response to the Call for Evidence: European Partnerships to be implemented as Joint Undertakings

General remarks

MedTech Europe welcomes the European Commission's initiative to establish a Single Basic Act (SBA) for Joint Undertakings (JUs) under the next Multiannual Financial Framework (2028–2034). Treaty-based European Partnerships are a cornerstone of the EU's research and innovation ecosystem, enabling collaboration between industry, academia, public entities, Member States, and EU institutions to address complex, cross-border challenges.

In the health domain in particular, partnerships are essential to mobilise the scale of expertise, investment, and infrastructure needed to deliver innovative medical technologies and solutions that improve patient outcomes, quality of life and strengthen health systems.

The current framework, particularly under Horizon Europe and the Innovative Health Initiative (IHI), is delivering strong results and demonstrates the value of this model. IHI has successfully brought together a broad health ecosystem (medical devices, in-vitro diagnostics (IVD), digital health, pharmaceuticals, vaccines, and biotechnology) while introducing more flexible call modalities and supporting important regulatory and cross-sector collaboration outcomes. For instance, the IHI community includes several hundred organisations across stakeholder groups (e.g. >400 large companies, >300 academic organisations, >200 SMEs, and >90 healthcare organisations), illustrating the scale and diversity of the collaboration enabled by the programme. For the medical technology sector in particular, participation in IHI has represented a significant learning process, allowing companies to better understand and engage in this collaborative model and progressively increase their contribution. A unique strength of IHI is its ability to align global industrial expertise, technologies and innovation capabilities around European healthcare priorities. Through the partnership model, European policy objectives are connected with world-class scientific, technical and implementation capabilities, amplifying the impact of both public and private investments.

For the medical technology sector, one of the most important achievements of IHI has been the successful integration of the medical technology sector into European health partnerships, enabling collaboration across medical devices, diagnostics, digital health, biotechnology and pharmaceuticals around shared healthcare challenges. This broader ecosystem approach represents a significant evolution compared to previous partnership models and has strengthened the ability of European stakeholders to address increasingly complex and interdisciplinary health challenges.

Building on this first positive experience, the medical technology industry is strongly committed to supporting the continuation and further development of the IHI model. Experience to date demonstrates that IHI provides unique added value by bringing together partners that would rarely collaborate otherwise, enabling the development of shared evidence, regulatory frameworks, data ecosystems and innovation pathways that cannot easily be created through conventional research funding instruments. Drawing on lessons learned and evidence from the implementation of IHI and other Joint Undertakings, there is a clear opportunity to enhance the effectiveness and impact of future JUs by making them more accessible, agile and investment-

friendly, while preserving and reinforcing the elements that are already working well. Future reforms should be evidence-based and build on demonstrated strengths and shortcomings of existing partnerships rather than introducing structural changes without a clear justification grounded in experience and evaluation.

The future SBA should therefore focus on simplification, flexibility, and impact-driven design, ensuring that JUs continue to deliver faster, more scalable, and more investable innovation outcomes. This evolution should be grounded in structured dialogue and co-creation with future partners, including industry, to ensure continuity, predictability, interest and strong commitment.

JUs should not be seen solely as funding instruments. From a health industry perspective, they represent one of the few structured environments where companies, SMEs, academia, healthcare providers, patients, regulators and public authorities can collectively identify systemic bottlenecks and address them at scale. This ecosystem function is particularly critical in the current policy context. While ongoing simplification efforts can reduce administrative burdens, they cannot by themselves create shared development pipelines, common standards or trusted collaboration frameworks. A future SBA should therefore be positioned as part of a broader competitiveness architecture, ensuring that regulatory simplification is complemented by strong, institutionalised partnership models capable of aligning research, validation, regulation, industrial capabilities and deployment.

Key messages:
Taken together, these recommendations are guided by three overarching principles: preserving what already works well in IHI, strengthening links between research and deployment, and ensuring that future reforms build on existing ecosystems, expertise and investments rather than replacing them.

- IHI has demonstrated its value as a collaborative public-private partnership, and future reforms should build on its strengths while being guided by *simplification* and *proportionality*;
- In-kind contributions should remain the core model and be recognised as *strategic capabilities*, supported by simplified and proportionate rules;
- *Mandatory* cash contribution should be avoided, as they risk reducing participation and diverting investments away from European Partnerships;
- Governance must be agile and reflect co-investment commitments;
- Stronger and clearer links to deployment and downstream financing instruments are essential;
- Member States should play a stronger operational role where they co-invest and support deployment;
- Timely and structured co-creation with industry is essential for securing future commitments.

Problem definition

MedTech Europe agrees that the future JU framework should become more efficient, accessible, agile and better connected to deployment mechanisms. However, several elements of the Commission's problem analysis do not fully reflect the experience and evidence generated by existing partnerships. Experience from IHI demonstrates that JUs already mobilise substantial private investment, expertise, infrastructure and collaborative capacity while delivering scientific, regulatory and ecosystem-level impacts. The challenge is therefore not primarily a lack of industry commitment, but rather how to maximise the value, deployment and reuse of these investments while preserving the strengths of the JU model. Many of the factors that originally justified the creation of IHI remain highly relevant today and should continue to underpin future reforms.

Complexity, accessibility and agility

Current JUs are characterised by complex governance structures, burdensome reporting requirements and fragmented rules, creating disproportionate administrative burdens and limiting attractiveness, particularly for SMEs, start-ups. In addition, lengthy timelines from project conception to grant signature and complex governance arrangements can reduce responsiveness to emerging scientific, technological and policy priorities.

Industry commitment and the value of in-kind contributions

The Commission identifies insufficient private co-funding as a key challenge. However, experience from IHI suggests that the principal issue is not a lack of industry commitment. Industry already contributes substantial financial resources as well as strategic capabilities such as expertise, infrastructure, datasets, technologies, development platforms, clinical networks and regulatory know-how. Many of these contributions cannot easily be procured or replicated through public funding alone, and their strategic value is not always fully reflected in traditional financial leverage metrics. A focus on mandatory cash contributions risks weakening participation, reducing flexibility and undermining the distinctive value proposition of the JU model.

Deployment and innovation impact

MedTech Europe agrees that stronger pathways from research to deployment are needed. However, limited deployment should not be interpreted as evidence that JUs are failing to deliver impact. IHI was designed primarily as a collaborative research and innovation partnership, and many of its impacts materialise through shared infrastructures, regulatory frameworks, evidence-generation methodologies, standards, data ecosystems and innovation de-risking mechanisms that enable subsequent investment, adoption and scale-up. The ultimate measure of success should be demonstrable real-world impact for patients and healthcare systems

Cross-sector collaboration and ecosystem impact

One of the major strengths of JUs is their ability to bring together industry, SMEs, academia, healthcare providers, regulators, public authorities and patient organisations around shared challenges. This ecosystem role is often difficult to capture through traditional funding metrics, yet it represents one of the most important sources of long-term impact. Through this collaborative model, IHI projects contribute to major EU priorities while creating trusted collaboration frameworks, reusable assets and shared capabilities that support European competitiveness beyond individual projects.

Objectives and policy orientation

MedTech Europe strongly supports the Commission's objective to enhance competitiveness through effective JUs. In health, a future partnership should act as a bridge not only across the research continuum but also towards deployment. This includes strengthening activities closer to deployment, including demonstration, clinical validation, regulatory science and real-world evidence generation, while ensuring structured connections to downstream European financing instruments that can support adoption, implementation and commercial scale-up. Evidence from IHI-supported projects demonstrates how JUs generate impact beyond research outputs by aligning regulators, HTA bodies, industry, academia, healthcare providers and patients around common frameworks, methodologies and evidence-generation approaches. Projects such as HEU-EFS and IDERHA illustrate how public-private partnerships can support regulatory convergence, reduce fragmentation, improve predictability of evidence requirements and accelerate innovation uptake. These outcomes demonstrate that JUs function not only as funding mechanisms but also as ecosystem coordination platforms that strengthen innovation, competitiveness and patient access. Future partnerships should

therefore preserve and scale this pre-competitive function, ensuring that validated outputs are systematically reused and connected to deployment instruments.

To achieve this, the future framework should prioritise:

- Full coverage of the innovation-to-investment pathway, including higher TRLs, demonstration, and deployment;
- Improved accessibility and openness, particularly for SMEs, start-ups, and new entrants;
- Increased speed and agility, including shorter time-to-grant and more flexible programming;
- Stronger global competitiveness, ensuring the EU remains an attractive hub for industrial R&I investment;
- An ambitious and predictable level of public and private investment in collaborative health innovation, reflecting the scale of future healthcare and competitiveness challenges;
- Better alignment with deployment instruments, notably the European Competitiveness Fund, to bridge the "valley of death".

Evidence and recommendations

While the first IHI projects have yet to be finalised, early evidence already points to strong performance. IHI represents a EUR 2.4 billion public-private investment combining EU, industry and partner contributions and has already supported 24 regulatory procedures, illustrating both its scale and its contribution to regulatory innovation. In addition, IHI-supported research is demonstrating high scientific impact, with a citation impact more than twice the world average (2.43x) and significantly above EU benchmarks, confirming both the quality of research outputs and the effectiveness of dissemination and knowledge transfer activities across stakeholder communities.

Beyond these quantitative indicators, projects across the portfolio are generating broader ecosystem impacts through regulatory alignment, real-world evidence generation, data infrastructure development, cross-sector collaboration and support for key EU policy initiatives such as the European Health Data Space (EHDS). These experiences demonstrate that IHI is already delivering value not only through research outputs, but also through the creation of trusted collaborative ecosystems, shared capabilities and innovation pathways that would be difficult to establish through conventional funding mechanisms alone.

The following recommendations build on MedTech Europe's experience in IHI and are intended to strengthen an already successful model. Future reforms should focus on enhancing the elements that have made IHI effective (collaboration, co-investment, industrial engagement and ecosystem building) while improving simplification, operational flexibility, deployment pathways and the recognition of strategic in-kind contributions.

1. Governance: towards simpler, faster, and more agile structures

The governance of future JUs should be significantly streamlined to improve efficiency, decision-making speed, and impact. In a rapidly evolving scientific and technological environment, governance arrangements must enable faster and more flexible priority-setting, allowing partnerships to respond effectively to emerging healthcare needs and innovation opportunities. While the Commission has identified limited steering capacity and flexibility as key challenges, addressing these should not rely solely on increased EU-level control. Instead, future partnerships should be based on balanced and effective co-governance between all governing partners, ensuring shared ownership and commitment. This is essential to ensure that JUs remain globally competitive and responsive to emerging challenges.

Governance arrangements should clearly reflect the level and nature of partners' commitments. Stakeholders contributing financial resources, in-kind assets, infrastructure, data or implementation capacity should have a commensurate role in decision-making. This principle is essential to maintain credible co-investment incentives. The experience of IHI illustrates this approach, where balanced representation between the European Commission and industry reflects the jointly funded nature of the partnership and underpins the willingness of industry to commit significant multiannual resources and strategic assets. Evidence from IHI shows that this alignment between governance and contributions is a key condition for mobilisation of proprietary datasets, platforms and expertise; where such alignment is weakened, participation risks becoming more transactional and less strategic.

Key principles should include:

- Shared strategic steering, with clear and balanced roles between public and private partners;
- Simplified governance structures, avoiding unnecessary complexity, especially where tripartite arrangements dilute accountability, slow processes and introduce significant operational complexity (such as state aid rules);
- Particular caution with full tripartite models: while Member State involvement can bring important value, it can also introduce fragmentation due to differing national rules, priorities, and funding conditions. This may impact access to talent across Member States and may make overall processes more difficult to manage and less predictable for participants;
- Where a tripartite model is implemented, roles and responsibilities should be clearly defined to ensure effective coordination and decision-making;
- Member States' involvement should focus on strategic alignment and deployment support, rather than participation in call-by-call funding decisions, which risks adding complexity, delays, and inconsistencies across projects;
- A more operational role for Member States where they co-invest can be valuable when linked to deployment capabilities (e.g. pilots, procurement pathways and healthcare system uptake), provided this does not fragment the core EU-level process;
- Large advisory bodies should be reconsidered in favour of more targeted and expert-driven mechanisms;
- Faster processes, including reduced time-to-grant and more agile call design;
- Adaptive programming, enabling partnerships to adjust priorities over time without adding complexity. At the same time, partnerships require predictable multiannual budget planning to provide contributors with the certainty needed to commit long-term resources and investments.

Member States can provide substantial added value through access to healthcare systems, real-world testing environments, procurement mechanisms, reimbursement pathways, data infrastructures and adoption ecosystems. Stronger alignment with national and regional initiatives can facilitate faster translation from research into adoption. However, experience across JUs shows that excessive fragmentation of roles and funding responsibilities across countries can undermine efficiency and predictability. A balanced approach is therefore required, linking governance involvement to concrete contributions while preserving a coherent and streamlined operational framework.

Concrete improvements could include:

- Greater use of applicant-driven, single-stage application processes, to accelerate time-to-grant, improve agility, and ensure that public funding is allocated efficiently to the most competitive and impactful projects;
- Increased reliance on independent expert evaluation, rather than large governance layers;

- More strategic and targeted involvement of Member States, focusing on programming and deployment rather than systematic participation in all governance structures or funding decisions at project level.

Such an approach would enhance responsiveness, improve efficiency, and preserve the collaborative added value of JUs, while strengthening their ability to deliver on EU strategic objectives.

2. Funding model: simplification and flexibility as key principles

A reformed funding model is essential to ensure that JUs remain attractive, predictable and capable of mobilising meaningful private investments at scale. MedTech Europe strongly supports maintaining in-kind contributions as the core principle of industry participation. At the same time, it calls for substantial simplification and increased flexibility in their valuation, allocation and reporting. This includes streamlined cost methodologies, alignment with industry accounting practices, reduced certification requirements, and greater flexibility in how contributions are allocated across projects and portfolios.

Beyond financial contributions, in-kind inputs should be recognised as a strategic capability at the core of the JU model. These contributions often consist of assets that public funding cannot procure, such as proprietary datasets, clinical and performance evidence, testing environments, manufacturing know-how, digital platforms, regulatory expertise and clinical networks, which are essential to achieving real-world impact in health innovation. The future framework should also better recognise the value of in-kind contributions originating from global companies outside the EU. Beyond their financial value, these contributions provide access to specialised expertise, technologies, development capabilities and global innovation networks that can significantly strengthen European research and innovation efforts. A key strength of IHI is its ability to align these global capabilities with European healthcare and competitiveness objectives. Such contributions can significantly increase the scale, quality and impact of collaborative projects while strengthening Europe's attractiveness as a destination for global R&I investment. A strengthened SBA should therefore go beyond accounting value and also capture their delivery, additionality, reusability and systemic impact, ensuring that investments translate into lasting European capacity and reduced duplication across the innovation landscape.

This is reflected in current participation patterns in IHI: large industry contributes approximately 80% of total contributions (combined in-kind and financial), while receiving a significantly smaller share of EU funding (around 15% of total requested EU contributions, and around 20% when including all founding and contributing partners). These figures demonstrate that the principal challenge is not a lack of industry commitment. Rather, the future framework should ensure that financial leverage assessments appropriately recognise the value of strategic in-kind contributions, including expertise, data, infrastructures, platforms and development capabilities that are often more important than cash in delivering public value and innovation impact.

The current valuation methodology may not fully capture the real economic value of in-kind contributions. Access to highly specialised expertise, regulatory know-how, proprietary platforms, clinical networks, data assets and development capabilities is typically accounted for at internal cost, although replacing these capabilities through external procurement would often involve significantly higher expenditure. As a result, the actual value transferred to collaborative projects is frequently greater than reflected in reported contribution figures.

The legislative framework should ensure that practical conditions allow private members to fulfil their commitments effectively. A specific issue concerns participants contributing in-kind without requesting EU

funding. The current framework does not provide a proportionate and differentiated status for such participants, resulting in unnecessary administrative burden. Establishing a distinct and streamlined participation status for these actors would significantly improve accessibility and encourage broader engagement, including from mid-sized companies, affiliates, and new entrants. Moreover, greater predictability in the application of funding rules and audit practices will be essential to allow participants to plan long-term engagement and avoid legal and financial uncertainty. More generally, the balance between obligations imposed on participants and the funding received should remain proportionate, as excessive administrative, legal or reporting requirements can undermine the attractiveness of participation and reduce willingness to commit strategic capabilities.

The framework should also create conditions that encourage companies to contribute their most valuable assets and capabilities, including proprietary data, expertise, platforms, infrastructures and development know-how. Overly burdensome rules, legal uncertainty or disproportionate obligations may discourage the mobilisation of these strategic resources, thereby reducing the broader public value and innovation impact that JUs are designed to generate.

Importantly, cash contributions as such are not problematic and are already an established element of IHI. However, *mandatory* cash contributions should be avoided. Imposing such requirements risks fundamentally changing the nature of JUs, shifting them away from collaborative co-investment models towards transactional funding arrangements. In addition, company-specific constraints must be taken into account: some industry participants are not permitted to provide cash contributions without highly specific contractual arrangements with predefined partners, which are not compatible with open, competitive EU project frameworks. A balanced approach is therefore needed, where the framework allows for voluntary cash contributions where appropriate, but avoids rigid, obligations that could significantly deter participation and reduce flexibility. While financial contributions can be important, the real strength of JUs is their ability to bring together industrial expertise, proprietary knowledge, data, technologies, research platforms and development capabilities that are otherwise unavailable to the public system. Addressing healthcare challenges requires access to these capabilities, clinical environments, regulatory expertise and implementation know-how; additional cash alone cannot replace them.

Key recommendations include:

- Maintaining a minimum in-kind contribution ratio to ensure balanced commitments across partners;
- Simplifying and harmonising cost categories across partnerships to reduce administrative burden;
- Introducing standardised or pre-approved cost models, including unit-cost approaches, to increase predictability and reduce reporting complexity;
- Aligning valuation methods with industry accounting practices to reduce uncertainty and administrative burden;
- Allowing greater flexibility to allocate contributions at portfolio level rather than strictly at project level to reach the mandatory contributions threshold;
- Preserving IKAA, but with significantly simplified certification and reporting requirements.

3. Accessibility and openness

Future JUs should be significantly easier to access, particularly for SMEs, start-ups, and new participants.

This can be achieved through:

- Simplified participation rules and reduced administrative requirements;
- Lower barriers to entry for new stakeholders;

- Greater flexibility in participation structures, including the possibility to group contributions across entities. This is especially relevant for larger industry partners participating with several entities in a single project;
- Continued use and further development of applicant-driven call modalities, as successfully implemented in IHI, combined with dedicated brokerage events and collaboration platforms that facilitate partner search and consortia building, thereby lowering entry barriers. IHI programme data shows substantial participation of new entrants across calls, demonstrating that these instruments are effective in opening the programme to newcomers.

At the same time, it is essential to preserve the international dimension of European Partnerships. IHI has demonstrated the value of attracting global expertise, investment and innovation capabilities into EU-led projects. Maintaining openness to international participation (and better recognition of on-EU in-kind contributions), where aligned with EU strategic interests, strengthens scientific excellence, increases scale and impact, and reinforces Europe's attractiveness as a destination for R&I investment.

4. Intellectual property: enabling, not discouraging, innovation

The intellectual property (IP) framework should incentivise participation and enable companies to bring forward their most valuable innovations. Experience with the current framework suggests that certain exploitation obligations, transfer restrictions and ownership requirements may create unintended barriers to participation, introduce legal uncertainty and reduce Europe's attractiveness for global R&I investment. While safeguards may be justified for genuinely strategic technologies, they should be applied in a proportionate and risk-based manner, with appropriate flexibility for projects outside critical technology domains.

The interaction between IP rules, Member State participation and state aid considerations also requires careful attention. While Member State involvement can support deployment and uptake, IP and access-rights arrangements should remain transparent, proportionate and linked to project objectives rather than levels of national co-investment. This is important to preserve a level playing field, avoid distortions of competition and ensure equal opportunities for participants across the Union.

Experience also indicates that insufficient distinction is sometimes made between research activities and commercial exploitation, or between strategic and non-strategic technology areas. Future frameworks should therefore adopt more targeted safeguards while preserving the flexibility required for effective management, transfer and exploitation of project results.

Key recommendations include:

- Flexible, project-specific IP arrangements;
- Legal certainty and protection of commercially sensitive information;
- Avoidance of overly rigid rules that discourage participation;
- Clear and transparent access-rights principles that prevent unequal treatment across Member States;
- A clever distinction between research use and commercial exploitation;
- Preservation of the ability to transfer ownership and reorganise IP portfolios where appropriate;
- Simplified and predictable waiver procedures for transfers or exploitation outside the EU where no strategic concerns exist;
- Risk-based safeguards focused on genuinely critical technologies rather than horizontal restrictions.

5. Cross-sector collaboration: value-driven approach

Cross-sector collaboration is a core and indispensable feature of European Partnerships and a key driver of innovation impact, particularly in health where solutions increasingly rely on the integration of technologies, disciplines and value chains (e.g. digital, AI, diagnostics, therapeutics, and healthcare delivery). Strengthening such collaboration must therefore remain a central objective of future JUs.

Evidence from IHI-funded research highlights the strong performance of cross-sector collaboration within the JU model, with a high proportion of projects involving multi-country and multi-sector partnerships (e.g. nearly 79% of publications involving international collaboration). This demonstrates the effectiveness of the JU model in integrating expertise across ecosystems and delivering collaborative outcomes at scale.

Building on this positive experience, it is also important to recognise that the impact of cross-sector collaboration depends on how it is operationalised in practice. Experience from current partnerships shows that approaches that are not sufficiently aligned with the specific objectives of projects can introduce unnecessary complexity or dilute focus. A more structured and purpose-driven implementation can therefore maximise its impact while preserving efficiency.

Cross-sector collaboration should therefore be:

- Systematically encouraged and embedded as a core principle of JUs, reflecting the need for integrated solutions to complex challenges;
- Driven by concrete use cases and clearly defined integration needs, ensuring meaningful collaboration between sectors;
- Proportionate to the objectives of each call topic and project, enabling the right level and type of cross-sector engagement;
- Implemented through well-designed calls, topics or modules that actively facilitate collaboration while maintaining clarity of purpose.

This approach ensures that cross-sector collaboration remains both ambitious and effective, reinforcing its role as a fundamental pillar of JUs while avoiding unnecessary complexity and maximising impact.

6. Portfolio approach and synergies

To address fragmentation and improve overall effectiveness, the future framework should introduce a pragmatic and flexible portfolio management approach across JUs. At present, partnerships may to operate in silos, limiting cross-fertilisation and reducing the ability to respond to cross-cutting challenges. At the same time, the design and scope of the future partnership landscape under FP10 remain to be defined, and the degree and nature of synergies will depend on how this landscape evolves. A portfolio approach should therefore be adaptive and driven by concrete added value, supporting coherence and synergies where relevant, while avoiding unnecessary coordination burdens.

This should include:

- Strategic coordination and alignment across partnerships at programming level, where thematic proximity or shared objectives exist;
- Mechanisms for joint programming, coordinated calls, or aligned roadmaps on a voluntary and needs-driven basis, particularly where clear complementarities can be identified;
- Tools to support knowledge sharing, re-use of results, and dissemination across partnerships;
- Continued encouragement of targeted collaboration with partnerships in other sectors, where cross-cutting challenges (e.g. digital, AI, sustainability, manufacturing) require coordinated approaches beyond the domain of a given partnership;

- Greater flexibility to reallocate priorities or launch cross-cutting initiatives in response to emerging needs.

Such a portfolio-level perspective would enable the EU to better leverage its investments and avoid duplication, while maintaining the sector-specific strengths of individual partnerships and ensuring that coordination efforts remain proportionate and impact-driven.

In practice, IHI projects already contribute to key EU priorities such as EHDS, AI and life sciences policy through work on health data, artificial intelligence and real-world evidence (RWE). Portfolio initiatives, like the IHI RWE Initiative, that connect related projects have demonstrated how knowledge sharing, policy engagement and reuse of results can increase impact, reduce duplication and strengthen sustainability beyond individual funding cycles.

This example demonstrates that IHI is already closely aligned with key EU strategic priorities in health, digitalisation, data governance and life sciences. Future reforms should therefore build on this established alignment while increasing responsiveness to new priorities as they emerge.

7. Strengthening the link to deployment and the European Competitiveness Fund (ECF)

A key priority for the future framework should be to bridge the persistent gap between research results and market uptake ("valley of death"). While current JUs have been effective in supporting early and mid-stage R&I, support for higher Technology Readiness Levels (TRLs) and deployment remains insufficient, limiting overall impact.

However, the objective should not be to transform JUs into deployment instruments per se. The primary strength of partnerships such as IHI lies in their ability to perform collaborative, pre-competitive research and innovation, build ecosystems, generate evidence, align stakeholders and de-risk innovation. Future partnerships should therefore support and enable deployment through validation, demonstration, regulatory science and evidence generation, while relying on dedicated downstream instruments such as the European Competitiveness Fund (ECF), InvestEU and European Investment Bank (EIB) mechanisms for large-scale commercial deployment and market uptake and scale-up. For medical technologies, this includes support for clinical validation, evidence generation, early feasibility studies, real-world evidence, healthcare adoption, procurement readiness and reimbursement pathways, which are often critical determinants of successful deployment.

Current IHI projects already demonstrate how public-private partnerships can generate shared infrastructures, regulatory science outputs, real-world evidence capabilities and data ecosystems that support deployment and implementation beyond individual project lifetimes. These investments contribute directly to major EU priorities, including EHDS, AI and life sciences policy objectives, while creating reusable assets and capabilities that support scale-up, adoption and competitiveness.

The future framework should also place greater emphasis on the reuse, scaling and sustainability of assets developed under previous and ongoing EU-funded initiatives. Too often, successful platforms, datasets, methodologies, standards, tools and collaborative networks created through earlier projects are not sufficiently leveraged by subsequent programmes, leading to duplication of effort and inefficient use of public and private investments. Greater attention should therefore be given to the systematic mapping, reuse and long-term exploitation of existing project outputs. New initiatives should be expected, where appropriate, to build upon proven assets and capabilities rather than recreating them. This would accelerate deployment,

improve return on investment, strengthen interoperability across projects and help create durable European innovation capacities beyond individual funding cycles.

This requires:

- Stronger and systematic integration with the ECF;
- Increased support for higher TRL activities, including clinical validation, demonstration, and real-world testing;
- Mechanisms to enable scale-up, industrialisation, and procurement readiness. For example, IHI projects demonstrate how partnerships can directly support regulatory implementation through sandboxes, health data frameworks and harmonised clinical evidence pathways;
- Mechanisms to identify, sustain and reuse high-value assets and results from previous EU-funded initiatives, including platforms, datasets, standards, infrastructures and collaborative networks, in order to reduce duplication and accelerate deployment;
- Stronger mechanisms to connect project outcomes with Member State deployment infrastructures, reimbursement pathways, procurement mechanisms and healthcare system adoption activities;
- Clear pathways for transitioning projects from R&I funding to deployment instruments.

Ensuring continuity across the innovation cycle will be critical to translating scientific excellence into tangible benefits for patients, healthcare systems, and European competitiveness.

This strengthened role should remain focused on pre-competitive collaborative activities where shared infrastructure and collective action are essential. The framework should maintain a clear distinction between such activities and firm-specific market deployment and commercial expansion, which is better supported through downstream instruments such as the ECF, InvestEU or EIB channels. This approach allows JUs to de-risk innovation without creating distortions of competition.

8. Dedicated Health Partnership with a strong medical technology dimension

MedTech Europe considers a dedicated Health Partnership essential for addressing complex health challenges and maintaining European competitiveness. Such a partnership should build on the strengths, achievements and established stakeholder ecosystem of IHI, while evolving its effectiveness, agility, deployment orientation and attractiveness for medical technology industry to maximise impact.

Medical technology innovation has specific characteristics, including regulatory complexity, relatively fast iteration cycles (particularly for incremental and digital technologies), the need for robust clinical evidence generation for high-risk technologies, and strong interaction with healthcare systems, reimbursement pathways and care delivery models. These characteristics require a dedicated and tailored partnership model that cannot easily be replicated through more generic research and innovation instruments.

The diversity of participation in IHI, including strong engagement from industry, SMEs, academia and healthcare stakeholders, demonstrates the relevance of maintaining a broad and inclusive partnership model for health innovation. IHI has been particularly important for integrating medical technology stakeholders into the European partnership landscape and fostering collaboration between device manufacturers, diagnostics developers, digital health actors, healthcare providers, regulators, academics and patients. Preserving this expanded ecosystem should remain a priority for future health partnerships.

Any streamlining of the JU landscape should be driven by demonstrable synergies and expected impact rather than administrative simplification alone. In highly regulated sectors such as health, the effectiveness of partnerships depends on specialised expertise, established stakeholder communities, regulatory engagement

and trusted collaborative structures. Reforms should therefore seek to reduce unnecessary duplication while preserving the critical mass, focus and ecosystem dynamics that make health partnerships effective.

IHI has established a trusted ecosystem across industry, academia, healthcare providers, regulators, patients and public authorities. Future reforms should build on this existing network and accumulated experience rather than recreate equivalent structures.

Such a partnership should:

- Extends its scope across the full innovation-to-investment pathway, including clear links to instruments such as the ECF;
- Maintain a strong focus on health while enabling targeted cross-sector collaborations where it delivers clear value, including digital, AI, environmental sustainability, and circular economy actors;
- Ensure that any consolidation of partnerships is evidence-based and preserves sector-specific expertise, stakeholder communities and implementation capacity;
- Ensure any expansion in scope remains purpose-driven and manageable, avoiding dilution of objectives or excessive complexity in governance and implementation;
- Retain sector-specific expertise and governance adapted to the needs of health innovation;
- Be supported by a specialised operational structure (e.g. dedicated office) with strong legal, financial, and scientific capabilities;
- Provide tailored rules and support mechanisms adapted to clinical research, regulatory pathways, and market access considerations;
- Ensure continuity with existing ecosystems and stakeholder networks built under IHI.

This approach would allow the partnership to increase its impact and relevance in addressing complex health challenges, while preserving the focus, efficiency, and attractiveness required to mobilise industry participation. Maintaining a dedicated and specialised structure will be critical to ensuring effectiveness, usability, and impact in a highly regulated and complex sector such as medical technologies and broader health innovation.

To reconcile long-term predictability with operational flexibility, a future health partnership could adopt an internal multi-track architecture. One track could support large-scale, long-cycle strategic programmes; a second could enable faster, challenge-driven or applicant-driven calls addressing emerging priorities; and a third could focus on demonstration, validation, regulatory science and deployment support where solutions are more mature and support from Member States will bring significant value. Such an approach would maintain strategic coherence at portfolio level while increasing responsiveness at instrument level.

Expected impacts

Implementing these recommendations would:

- Strengthen Europe's competitiveness by reinforcing Joint Undertakings as strategic platforms for cross-sector collaboration, industrial co-investment and ecosystem development and the mobilisation of global industrial expertise, technologies and innovation capabilities around European priorities;
- Increase private sector participation and mobilisation of strategic capabilities, including data, infrastructure, expertise, development know-how and other high-value in-kind contributions;
- Improve SME and ecosystem accessibility, enabling broader participation across the innovation landscape;

- Accelerate innovation cycles and reduce time-to-impact through more agile governance, simplified processes and flexible programming mechanisms;
- Enhance the translation of research into real-world impact, by strengthening links between collaborative R&I activities, validation, demonstration, deployment and downstream financing instruments;
- Improve alignment with Member States and healthcare systems, facilitating faster uptake, implementation and scaling of innovative solutions;
- Increase the reuse, sustainability and long-term value of assets, infrastructure, methodologies and collaborative networks developed through previous European investments;
- Reinforce Europe's leadership in health technologies, while helping ensure that the economic, societal and industrial value created from European research is captured within Europe;
- Deliver tangible benefits for patients and healthcare systems, including faster access to safe, effective and innovative healthcare solutions, recognising real-world patient and healthcare-system impact as the ultimate success metric of collaborative health innovation.

Process and need for structured co-creation

The design of the future Single Basic Act (SBA) should be firmly grounded in evidence and evaluation of existing partnerships. Joint Undertakings remain among the few EU instruments capable of combining strategic scale, long-term programming, cross-sector coordination and genuine co-investment between public and private actors. Building on these strengths will be essential to ensure continuity and effectiveness.

MedTech Europe understands that the Commission intends to first adopt, by the end of 2026, a legislative proposal establishing the SBA and identifying broad thematic areas for future Joint Undertakings (JUs) under the next Horizon Europe framework. Potential partnership candidates would then be invited to apply through a competitive selection process in 2027, for which the modalities, timelines, and evaluation criteria are not yet defined. It also remains unclear whether subsequent implementing acts, potentially in late 2027, would be foreseen to specify the detailed design, governance, and operational modalities of selected partnerships.

Greater clarity on this overall process is essential. Prospective founding members require early visibility on legal, financial, and governance obligations in order to secure internal approvals for long-term resource commitments. Without such clarity, there is a risk of misalignment between policy ambition and the ability of stakeholders to engage effectively.

This approach would represent a significant departure from the model followed for previous and current partnerships, including IMI and IHI. In those cases, the development of the legal framework was based on sustained, structured exchanges between the Commission and industry associations, covering the definition of scope, governance, financial architecture, and legal provisions. These interactions were critical to enable industry partners to assess risks, define commitments, and obtain the necessary approvals from their respective governance bodies. Given the scale and diversity of stakeholders involved, effective co-creation mechanisms are essential to ensure alignment, commitment, and long-term investment.

Such a process cannot be replaced by public consultations alone. While the Call for Evidence foresees additional targeted consultations, including with industry and representatives of existing JUs, important questions remain regarding their scope, format, timing, and level of influence on the design of future partnerships. The development of effective, fit-for-purpose JUs requires continuous, structured and sufficiently granular dialogue, rather than reliance on one-off or ad hoc consultation mechanisms.

In this context, MedTech Europe calls for:

- Early clarification of the design and timeline of the competitive selection process, including expectations for industry commitments;
- Transparency on whether and how implementing acts or equivalent instruments will define partnership-specific modalities;
- The establishment of a structured engagement roadmap between the Commission and prospective partners, enabling co-creation of partnership design;
- Dedicated technical exchanges to address lessons learned and operational challenges from IHI
- Early and timely clarity on legal, financial, and governance conditions to enable prospective partners to complete the necessary internal decision-making and approval processes for participation within the required timelines.

Ensuring a predictable, transparent, and co-creative process will be critical to securing strong and sustained industry engagement in future JUs and to maximising their impact. Without such structured engagement, there is a significant risk that future JUs will not fully mobilise the level of industry commitment required to achieve their intended impact.

Conclusion

MedTech Europe stands ready to engage with the European Commission and relevant stakeholders in shaping an effective and future-proof framework for Joint Undertakings under the next Horizon Europe programme.

A simplified, agile, and predictable Single Basic Act will be essential to ensure that European Partnerships remain attractive for private investment and capable of delivering impact at scale. Addressing Europe's future healthcare, demographic and competitiveness challenges will require an ambitious and sustained level of investment in collaborative health innovation that is commensurate with these challenges. In particular, enabling practical and proportionate conditions for participation, ensuring balanced co-governance, and strengthening the link between research, innovation and deployment will be critical to meet the EU's competitiveness objectives.

At the same time, timely clarity on legal, financial, and governance arrangements, combined with a structured co-creation process, will be indispensable to secure the level of industry commitment required. Without early visibility and sustained engagement, there is a risk that future Joint Undertakings will not fully mobilise the investment, expertise, and resources needed to achieve their intended impact.

MedTech Europe remains committed to contributing constructively to this process to ensure that future partnerships deliver tangible benefits for patients, healthcare systems, and Europe's global leadership in medical technologies.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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