All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 4: Advanced therapy medicinal products: Supporting manufacturing and clinical centre readiness in Europe

Expected outcomes

The action under this topic must contribute to several of the following outcomes:

- Availability of operational solutions, tools and standards and best practices including interoperable digital tools for process monitoring, quality control, traceability and workflow integration, that remove bottlenecks in advanced therapy medicinal product (ATMP) manufacture and scalability in compliance with Good Manufacturing Practices (GMP).These benefit industrial developers, including small and medium-sized enterprises (SMEs), contract development and manufacturing organisations (CDMOs), academic organisations, and other ATMP innovators.

- Validated reference use cases demonstrating how integrated manufacturing, regulatory and clinical-readiness solutions can accelerate the development and deployment of ATMPs across different therapeutic modalities, development stages, and manufacturing settings, benefitting all relevant stakeholders in the ATMP value chain.

- Recommendations on opportunities for harmonisation and simplification of regulatory practices for manufacturing ATMPs while continuing to meet high-quality standards to inform regulatory authorities and other decision makers.

- A collaborative framework to enhance cooperation between industry, academic/hospital centres, other relevant entities, and regulators.

- Improved readiness and capacity for clinical centres for multi-country clinical trials and for deployment of ATMPs in routine care, benefitting researchers, industrial developers, healthcare providers and patients, including paediatric patients.

Scope

Advanced therapy medicinal products (ATMPs)[1] covering gene therapies, cell therapies, and tissue-engineered products, as well as ATMPs with integrated medical device(s) (referred to as combined ATMPs), represent one of the most transformative innovations in modern medicine, offering new treatment options for many diseases and injuries, including some previously untreatable conditions. However, ATMPs rely on complex technologies and there are many challenges that hamper their development and access to patients. These include for instance hurdles related to standardisation, manufacturing scalability and reproducibility, limited clinical centre readiness for running regulatory-grade clinical trials and for healthcare treatment delivery, and a complex regulatory landscape. Additionally, there is insufficient integration of diagnostics, digital infrastructure and care workflows needed for instance for patient identification, treatment scheduling, and long-term follow-up.

[1] As defined in article 2 of the Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121)

INDICATIVE TEXT

There is also a need for a coordinated approach that cuts across the full ATMP value chain from research infrastructures to the regulation, manufacture, and deployment of ATMPs in routine care, to ensure that Europe can position itself as a leader in the ATMP sector, as called for in the Draghi report[2] on EU competitiveness.

The topic aims to fund research and innovation that support the scaling-up of the EU's R&D capacity and capability in the ATMP field and has two interconnected objectives:

1. manufacturing readiness;

and

2. improving clinical centre readiness for clinical trials and healthcare delivery.

Both objectives are important in ensuring a continuum from the manufacture of ATMPs to their use in clinics, and to supporting the establishment of a unified, coordinated ATMP ecosystem in Europe.

Applicants are required to choose one of the objectives (manufacturing readiness or clinical centre readiness) as a primary focus that drives their proposal. Nevertheless, as the topic addresses integration across the full ATMP value chain, applicants are also required to adequately address the other aspect of the topic as a secondary objective.

Objective 1: Manufacturing readiness

The objective is to address the bottlenecks that limit the industrialisation of ATMP manufacture, with a focus on scalable, standardised, cost-efficient, and regulatory-ready production.

To achieve this objective, applicants should consider the following activities:

- Identify bottlenecks limiting efficient scalable manufacturing and industrial production of ATMPs.
- Pilot solutions to address these bottlenecks. These include the development of tools/methods to support flexible manufacturing through automation, digital technologies, interoperable data capture, analytics and traceability systems.
- Progress promising platform technologies for ATMPs towards validation and analyse their potential impacts on regulatory assessment[3].
- Explore ways to improve manufacturing robustness, adaptability and transferability while facilitating the introduction of innovations after manufacturing has been established. This may include defining a set of measurable manufacturing performance indicators.
- Define quality control standards for ATMP manufacture, including chemistry, manufacturing, and control (CMC) criteria for:
    - increased translatability, scalability, and robustness of flexible manufacture (including point-of-care manufacture) and deployment of ATMPs in a patient-centric manner;
    - integrating either computational modelling, automation, robotics or digital/artificial intelligence solutions;
    - promoting sustainable production and circular economy principles to minimise environmental impacts.
- Develop and validate rapid, fit-for-purpose quality control and product release approaches, including risk-based strategies and validated alternative analytical methods (where scientifically justified), to enable timely patient access while maintaining quality, safety and efficacy.

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[2] https://commission.europa.eu/topics/competitiveness/draghi-report_en

[3] In line with EMA regulatory science research needs NT3 https://www.ema.europa.eu/en/documents/other/regulatory-science-research-needs-2025-update_en.pdf

- Develop enabling standards where appropriate, including standards and interoperability for key technologies for the delivery of ATMPs, such as 3D bioprinting, bioreactors, guided in-vivo delivery/cell tracking, cold chain technologies, automation and robotics, etc. including interoperability of digital manufacturing and quality data.
- Validate the developed innovative manufacturing solutions, quality control and product release concepts, through representative ATMP technology demonstrators. These could be for example viral-vector-based gene therapies, genetically modified cell therapies, tissue-engineered products, and combined ATMPs. The demonstrators should collectively cover different manufacturing models, including centralised and, where relevant, decentralised or point-of-care manufacturing, and different stages from process development to clinical manufacturing to generate evidence for regulatory acceptance and future implementation in routine clinical practice.
- Develop a collaborative framework to foster cooperation between industry, academic/hospital centres and other relevant entities with a view to sharing data and best practices for efficient scale-up and deployment. This collaborative framework should also allow for early interactions with regulators.
- Develop evidence-based recommendations on opportunities for the harmonisation and simplification of regulatory practices and processes for manufacturing ATMPs to reduce duplication and accelerate patient access while continuing to meet high quality standards.

Objective 2: Improving clinical centre readiness for clinical trials and healthcare delivery

The objective is to increase treatment centre readiness for conducting multi-country and/or cross-border clinical trials and for delivering healthcare.

To achieve this objective, applicants should consider the following activities:

- Identify the barriers to treatment centre readiness and capability to conduct regulatory-grade clinical trials for ATMPs, deliver healthcare treatments, and conduct long-term follow up activities that could also enable care in outpatient settings when appropriate. These include barriers related to operational readiness (including clinical responsibility and liability), quality oversight, logistical constraints, operational coordination, and the interface between industrial manufacturing and clinical centres and the implementation of decentralised manufacturing where appropriate.
- Develop a framework to increase the capacity of European treatment centres to participate in multicentre, multi-country clinical trials for ATMPs and to deliver ATMPs in routine care, including quality management, digital infrastructure and operational models supporting point-of-care manufacture where appropriate. This framework should include the necessary tools, education and training, and best practices to strengthen operational readiness, workforce capabilities, and deployment. The framework should also establish a pathway to support the integration of diagnostics, imaging, medical technologies and digital solutions into end-to-end clinical workflows, from referral and eligibility assessment to treatment delivery and long-term follow-up.
- Pressure test the developed clinical-centre readiness framework through representative ATMP implementation use cases covering different treatment pathways, logistical requirements, patient populations, and care settings, including outpatient delivery where appropriate.
- Explore opportunities to define common approaches to foster the use by the treatment centres of existing registries for long-term follow-up, as a key source of real-world data, including linkage of treatment, diagnostics, imaging, and device-generated and patient-reported data where appropriate. This will support benefit-risk monitoring of ATMPs and address anticipated HTA and payer needs (e.g. data standardisation and data sharing/access to data).
- Support prospective multicentre clinical validation of innovative manufacturing, quality control and product release concepts to generate evidence for regulatory acceptance and future implementation in routine clinical practice.

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Applicants are expected to consider the potential regulatory impact of the anticipated project's outputs, and, as relevant, develop a regulatory strategy and interaction plan for generating appropriate evidence and for engaging with regulators and other bodies in a timely manner, e.g. EU national competent authorities, notified bodies for medical devices and *in-vitro* diagnostic devices, health technology assessment (HTA) agencies, and the European Medicines Agency (EMA) through existing opportunities for regulatory support services, such as the Innovation Task Force and qualification advice.

Applicants are also expected to explore and/or implement synergies and complementarities with relevant initiatives/projects at national, European, and international level, thus avoiding unnecessary overlap and duplication of efforts and funding. These include those addressing rapid manufacturing, decentralised manufacturing, digitalisation, and quality control. Applicants should also consider the relevant IMI and IHI projects on ATMPs and build on their achievements when relevant, as well as creating synergies with the upcoming Coordination and Support Action for establishing a European Network of Centre of Excellence, funded under the Cluster 1 Horizon Europe Work Programme 2026. Moreover, the project selected under this topic is expected to contribute to the Advanced Therapies Competitiveness Coordination Tool initiative[4] fostering its objective of creating a more coordinated ecosystem of ATMP research & innovation in Europe.

Expected impacts

The action under this topic is expected to achieve the following impacts:

- strengthening EU competitiveness in ATMPs through regulatory streamlining, manufacturing standardisation, innovative manufacturing and quality assurance approaches, and centre readiness for multi-country and/or cross border clinical trials and healthcare delivery;
- strengthening the EU health industries' competitiveness by removing operational manufacturing bottlenecks and facilitating scale-up, while maintaining the quality, safety and efficacy of ATMPs;
- reducing the development risk, timelines and costs of ATMPs through validated and transferable best-practices being taken up across Europe while anticipating HTA and payer needs;
- benefits to patient through access to ATMPs, including for common diseases;
- benefits to healthcare systems through earlier adoption of lifesaving ATMPs, reducing disease burden in non-communicable diseases and regenerative medicine (including rare and ultra-rare diseases).

Furthermore, the action to be funded under this topic is expected to contribute to the:

- Pharmaceutical Strategy for Europe (modernise the regulatory framework to improve patient access to ATMPs)[5];
- The proposed EU Biotech Act[6] (strengthening the EU Biotech Sector to ensure patient access to ATMPs);
- EC's Strategy for European Life Sciences (integrating the entire life sciences value chain)[7];
- Horizon Europe (2028-2034) (prioritising ATMPs as a strategic investment area)[8].

INDICATIVE TEXT

[4] https://commission.europa.eu/topics/competitiveness/competitiveness-coordination-tool-projects_en

[5] https://health.ec.europa.eu/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu/pharmaceutical-strategy-europe_en

[6] https://health.ec.europa.eu/document/download/ec1475b7-e3f9-409e-b927-fc7e69306a8c_en?filename=biotech_reg-com2025-1022_act_en.pdf

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52025DC0525&qid=1762330863739

[8] https://commission.europa.eu/strategy-and-policy/eu-budget/long-term-eu-budget/eu-budget-2028-2034_en

Why the expected outcomes can only be achieved by an IHI JU action

To realise the EU's potential as an attractive place to develop ATMPs requires expertise, resources, and knowledge from all stakeholders in the innovation value chain, including SMEs, biotech scale-ups, CDMOs, and equipment or technology suppliers alongside pharmaceutical and med tech companies and hospitals.

IHI JU provides a unique framework to stimulate a co-creation/co-ideation approach, bringing together the private (pharmaceutical and medical technology industry sectors) and public partners (academia, healthcare professionals and providers, patients and carers) as well as small and medium-sized enterprises (SMEs), regulatory authorities, health technology assessment bodies, payers, and charitable foundations / philanthropic organisations, with a view towards ensuring that the solutions developed are comprehensive, evidence-based, and aligned with public health needs whilst offering new market opportunities to companies.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI JU of up to EUR 10,389,000.

IHI JU estimates that an IHI JU financial contribution up to EUR 10,389,000 would allow a proposal to address the outcomes appropriately and achieve the expected impacts. Applicant consortia must ensure that at least 45% of the action's eligible costs and costs for the action related additional activities are provided by in-kind contributions to operational activities ('IKOP'), financial contributions ('FC's), or in-kind contributions to additional activities ('IKAA'). However, while 45% is the threshold for eligibility, applicant consortia are strongly advised to aim for 50% to adequately support the ambition of the research in question and reflect the true public-private dimension, as well as to provide a margin, e.g. for unforeseen changes during the project lifetime. IKOP and FCs may be contributed by the constituent and/or affiliated entities of both the IHI JU private members[9] and the contributing partners. IKAA may be contributed by constituent and/or affiliated entities of the IHI JU private members only. Contributing partners and/or their affiliated entities cannot contribute IKAA. See the call conditions in the annual Work Programme for further information (also in the document 'call text' published on the IHI JU website).

Indicative duration of the action

Applicants should propose a project duration that matches the proposed project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the conditions of the calls and call management rules under 'Specific conditions on availability, accessibility and affordability' do not apply.

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[9] The IHI JU private members are the industry associations representing the sectors involved in healthcare, namely COCIR (medical imaging, radiotherapy, health ICT and electromedical industries); EFPIA, including Vaccines Europe (pharmaceutical industry and vaccine industry); EuropaBio (biotechnology industry); and MedTech Europe (medical technology industry).

Legal entities established in Japan

According to the conditions of the calls and call management rules under ‘Entities eligible for funding’, legal entities participating in this topic and established in Japan are not eligible to receive funding.

Legal entities established in the Republic of Korea

According to the conditions of the calls and call management rules under ‘Entities eligible for funding’, legal entities participating in this topic and established in the Republic of Korea are not eligible to receive funding.

Legal entities established in Switzerland

According to the conditions of the calls and call management rules under ‘Entities eligible for funding’, legal entities participating in this topic and established in Switzerland are not eligible to receive funding.

Legal entities established in Australia

According to the conditions of the calls and call management rules under ‘Entities eligible for funding’, legal entities participating in this topic and established in Australia are not eligible to receive funding.

Glossary

Acronym	Meaning
ATMPs	Advanced therapy medicinal products
CMC	Chemistry, Manufacturing and Control
GMP	Good Manufacturing Practices
EMA	European Medicines Agency
EU	European Union
FC	financial contribution
HTA	Health Technology Assessment
IHI JU	Innovative Health Initiative Joint Undertaking
IKAA	in-kind contributions to additional activities
IKOP	in-kind contributions to operational activities
SMEs	Small & Medium-sized Entreprises

TEXT