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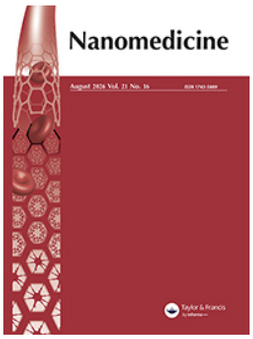
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The Italian Nanomedicine Platform (INP): national integration within the European nanomedicine ecosystem

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ABSTRACT

Italy's nanomedicine expertise has long developed in fragmented manner, with limited coordination across academia, clinical institutions, industry and regulatory bodies. The Italian Nanomedicine Platform (INP) was established to integrate discovery, preclinical validation, regulatory science and industrial translation within a single ecosystem aligned with Horizon Europe Cluster 1. We report the proceedings of the First INP Meeting (Rome, 16–18 Feb 2026), encompassing keynote contributions from European and international leaders, a national pitch session mapping institutional capabilities, and results from a structured inaugural survey. The meeting gathered ~140 principal investigators from nearly 100 institutions and formalized eight thematic Working Groups. A subsequent registration round reached 170 participants from 109 institutions. Over 60% of declared activity concerns nanomedicine products, physicochemical characterization, cell-based models and imaging, whereas regulatory science, AI and Health Technology Assessment remain under-represented (10–25%). The Technology Readiness Level distribution is markedly skewed toward early stages (~80% at TRL 1–4). Keynote speakers identified translational bottlenecks in GMP scalability, regulatory harmonization, mRNA–LNP technologies and clinical validation, concluding with a 24-month implementation roadmap. INP represents a strategic national node that converts distributed excellence into coordinated translational impact, explicitly addressing persistent bottlenecks in manufacturing, regulation and clinical validation.

PLAIN LANGUAGE SUMMARY

Nanomedicine comprises the development and therapeutic application of engineered nanocarriers, nanostructured biomaterials, and diagnostic nanosystems that exploit size-dependent physicochemical properties and biomolecular targeting strategies to enhance drug efficacy and imaging specificity while minimizing off-target effects and improving pharmacokinetic profiles. In Italy, many research groups work in this field, but until recently they were not well connected. The Italian Nanomedicine Platform (INP) was created to link scientists, clinicians, companies and regulators into a single national network, following the example of similar platforms already active in other European countries. This article summarizes what emerged from the first national meeting of INP, held in Rome in February 2026, and from a survey of the people and institutions that joined the platform in the following weeks. Italy shows strong skills in designing nanoparticles, testing them in advanced laboratory and animal models, and developing new therapies. However, most projects are still at an early stage and few have reached large-scale manufacturing or clinical use. International experts who attended the meeting highlighted both the scientific quality of Italian research and the practical obstacles, such as access to manufacturing facilities that meet Good Manufacturing Practice (GMP) regulatory standards, that slow the journey from the laboratory to the patient. By coordinating these efforts through eight thematic Working Groups and a shared roadmap, INP aims to help safe and effective nanomedicine technologies reach patients more quickly, both in Italy and across Europe.

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Nanomedicine; Italian Nanomedicine Platform; European Technology Platform for Nanomedicine; lipid nanoparticles; translational research; regulatory science; Horizon Europe; research infrastructure

1. Introduction: from a fragmented landscape to a national platform

The establishment of the Italian Nanomedicine Platform (INP) represents a strategic response to the long-standing fragmentation of the national nanomedicine landscape. Despite internationally recognized scientific excellence in nanotechnology, drug delivery, biomaterials and biomedical engineering, Italian research in this field has historically evolved in a dispersed manner, limiting translational convergence and

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Proceedings of the Rome Meeting (16–18 February 2026) and results of the inaugural platform registration survey On behalf of the Italian Nanomedicine Platform (INP) Organizing Committee, Working Group Coordinators and Meeting Participants

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Article highlights

Background and rationale.

- Despite internationally recognized research output, Italian nanomedicine has historically developed without a unifying national structure – a gap explicitly noted within ETPN discussions.
- INP was established as a national coordinating node spanning discovery, preclinical validation, regulatory science and industrial translation, aligned with Horizon Europe Cluster 1 priorities.

The First INP Meeting (Rome, 16–18 February 2026).

- The meeting gathered ~140 principal investigators from nearly 100 institutions and formalized eight thematic Working Groups.
- European and industrial keynote speakers (ETPN, Chiesi Farmaceutici, UMC Utrecht, University of Padua/MetabERN, Nanobiotix) framed national priorities within EU translational and regulatory strategy.

Platform identity and ecosystem mapping.

- A subsequent registration round recorded 170 participants from 109 institutions (~65% from universities), confirming a broad, distributed and nationally representative network rather than a small pilot group.
- Declared expertise is concentrated in nanomedicine products, physicochemical characterization, cell-based models and imaging (>60%), with drug delivery, biomaterials, *in vivo* models and extracellular vesicles strongly represented (40–60%).
- The TRL distribution of member projects is skewed toward basic research and proof-of-concept (~80% at TRL 1–4), with only a handful of projects approaching industrial scale-up or market readiness.

Governance, infrastructure and roadmap.

- Eight Working Groups, each coordinated by a Chair, two Vice-Chairs and a Young Spokesperson, are organized into three macro-platforms: NanoMed Solutions, Validation; Quality, and Translation, underpinned by a cross-cutting Education and Training axis.
- A mapped network of research infrastructures spans nanoparticle production, micro/nanofabrication, physicochemical and analytical characterization, biological/preclinical validation, advanced imaging, and GMP-oriented scale-up.
- A dedicated Good Laboratory Practice (GLP)-certified testing facility is also available through TransMed Research at the Tecnopolo di Bologna-Ozzano. This facility has established a track record of GLP-compliant studies on nanomedicines and nanostructured biomaterials for regenerative medicine applications, in active collaboration with universities, public research institutions and industrial partners.
- A 24-month roadmap defines governance formalization, a national characterization ring-study, a White Paper, GMP pilot collaborations and at least three multicentre translational projects (rare diseases, CNS, oncology).

system-level impact. Within the European Technology Platform for Nanomedicine (ETPN), the absence of a structured Italian national platform was repeatedly highlighted as a critical gap, in contrast with several other European countries that had already organized national ecosystems, including NanoMed Spain, NanoMed North, NanoMedicine Austria, the British Society for Nanomedicine, the French Society for Nanomedicine, and the German platform NanoBioMedizin. Among these, NanoMed Spain and NanoMedicine Austria have demonstrated successful models for bridging the Technology Readiness Level (TRL) 3–6 gap through coordinated national funding calls, shared access to preclinical and manufacturing infrastructures, and structured pre-competitive engagement with industry partners; strategies that INP explicitly adopts as reference models for its own translational roadmap.

INP was conceived as a national coordinating structure capable of integrating discovery science, preclinical validation, regulatory science and industrial translation within a shared framework aligned with Horizon Europe priorities, in particular Cluster 1 (Health). Three founding aims guided its design: (i) creating a technical-scientific community for the development of advanced and precision-medicine products across the therapeutic, diagnostic and preventive fields; (ii) systematizing synergies among the skills and technologies available across universities and centers of excellence; and (iii) ensuring coverage of the entire development pathway, from basic research and formulation chemistry, through preclinical testing, to high Technology Readiness Levels (TRLs).

An early, concrete demonstration of this coordination capacity preceded the meeting itself. Under the coordination of a Farmindustria member, and with contributions from Bracco Imaging, Dompé Farmaceutici, Fondazione Don Gnocchi, GSK, Menarini, Pfizer, the University of Modena and Reggio Emilia, the University of Naples Federico II, and Vertex Pharmaceuticals, a dedicated chapter on nanomedicine was published within the AIRI (Associazione Italiana per la Ricerca Industriale) volume 'Le innovazioni del prossimo futuro' (XI edition, dedicated to pharmaceuticals as a strategic asset for the country's economy), signaling early cross-sector alignment ahead of the platform's formal launch.

The First INP Meeting (Rome, 16–18 February 2026) marked the transition from conceptual initiative to operational ecosystem, providing the first systematic and shared mapping of competencies across the Italian nanomedicine community. By bringing together academic researchers, clinicians, industrial actors, regulatory representatives, and European stakeholders, the meeting enabled a comprehensive assessment of strengths, gaps, and opportunities across the full nanomedicine value chain and embedded the Italian network within the broader European nanomedicine strategy. This article reports the proceedings of the meeting together with the results of the platform's inaugural registration survey, and outlines the policy and innovation vision that emerged for the platform's first phase of activity.

2. Methods

The present article reports the proceedings of the First INP Meeting (Rome, 16–18 February 2026) and the results of the platform's inaugural registration survey. The meeting program comprised three main components: (i) keynote contributions from invited European and international leaders; (ii) a national pitch session in which principal investigators presented three-minute summaries of their research programs; and (iii) a structured policy and innovation session concluding with the presentation of a national roadmap. The Organising Committee transcribed and thematically synthesized the contributions. A structured online registration survey was distributed to all meeting attendees and subsequently to the broader Italian nanomedicine community via institutional and professional networks. The survey

collected self-reported data on: institutional affiliation and type; professional role; declared areas of expertise and research activity (mapped to 22 predefined categories); Technology Readiness Level (TRL) of the respondent's main research output (nine-level OECD/EU scale, TRL 1–9); preferred Working Group(s); and collaboration interests. The survey remained open for four weeks following the meeting and reached 170 registered participants from 109 unique institutions. Response rates varied by question: 139 participants (81.8%) completed the institutional typology item and 163 (95.9%) completed the professional role item. Descriptive statistics (absolute frequencies and percentages with denominator stated explicitly) were used throughout. No inferential statistics were applied. Qualitative synthesis of meeting content was performed by thematic review of session notes and presentation materials.

3. The European strategic framework: keynote contributions

Keynote contributions from European and international leaders framed INP within a wider continental strategy to strengthen translational nanomedicine through coordinated national nodes. Speakers reinforced the need for governance models able to synchronize scientific excellence with regulatory readiness and industrial scalability, positioning INP as a natural interface between Italian stakeholders and European initiatives.

3.1. Alexandre Ceccaldi (ETPN): the European strategic framework

Alexandre Ceccaldi, General Secretary of the European Technology Platform for Nanomedicine (ETPN), opened the keynote session with a strategic overview of the European nanomedicine landscape. His presentation contextualized INP within Horizon Europe Cluster 1 priorities, emphasizing advanced therapeutics, nano- and gene-delivery systems, biomanufacturing, regulatory science and precision medicine. Ceccaldi underscored the role of national platforms as coordinated nodes within the European network, facilitating cross-border collaboration, participation in EU calls, and harmonization of regulatory and characterization standards. The integration of INP into the ETPN ecosystem was presented as a strategic step toward increasing Italian participation in collaborative European projects, with the ETPN White Paper initiative highlighted as a tool for international visibility and policy dialogue.

3.2. Diego Ardigò (Chiesi Farmaceutici): rare-disease translation and industrial strategy

Diego Ardigò (Chiesi Farmaceutici) presented the PLUTO project as a translational case study in rare diseases, illustrating how nanomedicine-based approaches can be advanced from early discovery toward clinical and regulatory readiness. He highlighted the regulatory complexity associated with advanced therapies, the chemistry, manufacturing and controls (CMC) challenges specific to nanoparticle-based products, and the need to consider industrial feasibility from the earliest technology readiness levels onward.

3.3. Raymond Schiffelers (UMC *U*trecht): mRNA-LNP and in vivo CAR-T platforms

Raymond Schiffelers (UMC Utrecht) detailed the evolution of lipid nanoparticle (LNP) systems for mRNA delivery and next-generation *in vivo* CAR-T approaches. His presentation emphasized formulation science, ligand-based targeting strategies for extrahepatic delivery, and the regulatory harmonization required to bring these platforms from preclinical proof-of-concept to clinical application.

3.4. Maurizio Scarpa (MetabERN, University of Padua): clinical reverse pitch and the ERN perspective

Maurizio Scarpa (MetabERN, University of Padua) articulated clinical needs from the hospital and patient perspective through a 'reverse pitch' format, in which clinical unmet needs were presented to the research and industrial community. He called for multicentre validation, reproducibility of preclinical findings, and alignment with European Reference Network (ERN) requirements for rare and complex diseases.

3.5. Laurent Lévy (nanobiotix, ETPN chair): industrial selection criteria for nanomedicine projects

Laurent Lévy (Nanobiotix, Chair of ETPN) closed the keynote session by outlining the criteria industry typically applies when selecting nanomedicine projects for further development: scalability of the manufacturing process, clinical differentiation versus existing standards of care, regulatory clarity, robustness of intellectual property, and overall economic sustainability. These criteria were proposed as a practical filter for prioritizing projects emerging from the INP Working Groups.

4. Platform identity and participation: who we are

Following the keynote session, a national pitch session allowed principal investigators to present their research in three-minute formats, mapping national expertise across lipid nanoparticles, extracellular vesicles, nanoceria, regenerative biomaterials, RNA delivery systems and advanced imaging. The session demonstrated strong scientific depth across the country but also identified fragmentation in regulatory and GMP infrastructures as a recurring theme, addressed in detail in Section 4.

In the weeks following the meeting, an open registration round consolidated the emerging platform membership. At the time of writing, INP comprises 170 registered participants from 109 unique institutions. Of these, 139 participants (81.8% response rate) completed the institutional typology item of the registration survey (average of ~1.3 respondents per institution; representing 109 distinct institutions across 15 Italian regions), confirming a broad, distributed and nationally representative network rather than a concentration of activity in a small number of centers (Table 1).

Table 1. Institutional typology of INP registrants by self-reported institution type ($n = 139$ survey respondents; response rate 81.8% of 170 registered participants; 109 institutions).

Institutional type	Participants	Share of total
Universities	91	~65%
Research institutes (CNR, IRCCS and other independent research bodies)	22	~16%
Other (mixed entities, companies, departments not clearly classifiable)	25	~18%
Public health / government bodies	1*	<1%

*Explicitly classified via naming pattern; members of the Istituto Superiore di Sanità (ISS) are partly counted within the research-institute category due to the naming format used in the registration database.
Abbreviations: TRL: Technology Readiness Level. INP: Italian Nanomedicine Platform.

Table 2. INP membership by professional role (self-reported at registration; $n = 163$ respondents; 95.9% response rate of 170 registered participants).

Role	Participants	Share of total
Professor	66	~40.5%
Researcher	54	~33.1%
PhD student	11	~6.7%
Industry partner	9	~5.5%
Postdoctoral researcher	7	~4.3%
Clinician	1	~0.6%
Other	15	~9.2%

Abbreviations: INP: Italian Nanomedicine Platform.

The membership is led by senior academic staff: 66 full or associate professors and 54 researchers, alongside 11 PhD students, 9 industry partners, 7 postdoctoral researchers, 1 clinician, and 15 participants classified as 'other' (Table 2). The academic sector therefore forms the structural backbone of the platform, while industry, clinical and early-career representation, although present, remain comparatively limited and are a focus of the human-capital actions described in Section 7.6.

Participants were also asked to indicate the approximate Technology Readiness Level (TRL) of their main research output. Of 222 declared projects/outputs, 83 (37%) were classified as TRL 1–2 (basic research), 95 (43%) as TRL 3–4 (proof of concept), 39 (18%) as TRL 5–6 (preclinical validation), 3 (1%) as TRL 7–8 (clinical/industrial scale-up), and 2 (1%) as TRL 9 (market-ready). This distribution confirms that the platform's collective output is concentrated at early-to-intermediate maturity, with translational and market-ready activities still representing a small minority, a finding that directly informed the policy priorities discussed in Section 6.

5. Mapping the Italian nanomedicine ecosystem

The combination of the national pitch session and the registration survey allows, for the first time, an integrated picture of the Italian nanomedicine ecosystem across the full value chain, from fundamental chemistry and nanomaterials engineering, through drug formulation and biological validation, to translational and public-health perspectives. Six domains emerged as particularly relevant and are summarized in the following subsections.

5.1. Nanocarrier engineering and drug delivery systems

Italian research groups demonstrate deep expertise in the design and engineering of nanocarriers for drug, gene and protein delivery, including lipid-based nanoparticles, polymeric systems, bioinspired vesicles, hybrid nanostructures and multifunctional nanocomposites. These platforms address diverse administration routes, parenteral, pulmonary, topical, nose-to-brain and implantable, often supported by advanced surface functionalisation and targeting strategies. These activities are underpinned by consolidated expertise in formulation science and physicochemical characterization, positioning this domain among the most scientifically mature within the national landscape: according to the registration survey, nanomedicine products and physicochemical characterization are the two most frequently declared areas of activity, each represented in over 60% of responses. Research priorities include targeted delivery strategies, RNA- and mRNA-based therapeutics, and precision approaches for oncology, inflammatory diseases and neurological disorders. Nevertheless, most initiatives remain confined to early and intermediate TRLs, reflecting limited access to standardized scale-up and GMP infrastructures (Section 5.5).

5.2. Biomaterials, nanocomposites and nano-enabled therapeutics

Complementary strengths are observed in biomaterials, nanocomposites and functional nanostructures that extend beyond classical drug delivery. Bioactive inorganic nanomaterials such as nanoceria, stimuli-responsive polymers, nanocomposite scaffolds, injectable hydrogels and electroresponsive materials support applications in regenerative medicine, locoregional cancer therapy and theranostics. These activities illustrate a convergence of materials science, pharmaceutical technology and biomedical engineering, and were reflected in the registration survey by strong interest in the Bio/NanoMaterials and Regenerative Medicine Working Groups (89 and 46 expressions of interest, respectively; Section 6.1). Innovative research on inorganic and hybrid nanomaterials, nanozymes and theranostic platforms predominates at proof-of-concept level, with increasing interaction with biomedical and translational applications.

5.3. Preclinical validation and nanosafety

Preclinical validation and nanosafety assessment constitute a crucial enabling pillar of the ecosystem, strongly represented in 40–60% of declared activities. National expertise encompasses advanced *in vitro* and *in vivo* models, including three-dimensional cultures, organ-on-chip platforms and disease-relevant animal models, along with biodistribution, pharmacokinetic and toxicological studies broadly aligned with international regulatory frameworks. Patient-derived organoids and reconstructed tissue models enable increasingly physiologically relevant evaluation of nano–bio interactions, therapeutic efficacy and nanosafety, supporting reproducibility, biological relevance and regulatory relevance. However, fragmented infrastructures and the lack of harmonized protocols currently limit reproducibility and scalability, highlighting the need for coordinated platform-level actions such as inter-laboratory characterization ring-studies (Section 7.4).

5.4. Clinical translation

Clinical translation activities are emerging across selected therapeutic areas, notably oncology, rare diseases and chronic inflammatory conditions. Academic clinical centers and industrial partners contribute to early validation pipelines, and some industrial technologies – such as implantable and long-acting nano-enabled delivery systems and GMP-compatible nanovesicles positioned at TRL 5–7, provide concrete evidence that Italian nanomedicine is capable of near-term clinical and industrial impact. Despite this, broader clinical impact remains constrained – with only ~18% of declared collaborations involving clinical partners (28 of 159 collaboration preferences), compared to 57% for academic partnerships – primarily due to regulatory complexity and insufficient integration between preclinical research, manufacturing capabilities and clinical validation pathways. Consistent with this, the registration survey recorded only 24 expressions of interest in the Clinical Translation Working Group – the second-lowest among the eight WGs – and clinical collaborations represented only ~18% of declared collaboration interests (Section 7.3).

5.5. Manufacturing, scale-up and GMP

Manufacturing, scale-up and GMP-oriented development represent the most critical bottleneck within the current ecosystem. While emerging expertise in microfluidic nanoparticle production (e.g., NanoAssemblr-type platforms), continuous manufacturing and process optimization is present across several nodes, access to certified GMP facilities (Class B clean rooms, sterile formulation units, CMC workflows, lyophilization systems) and standardized production workflows remains limited at the national level. Within the registration survey, only 22 participants expressed interest in the Regulatory and Industrial Transfer Working Group – the lowest figure among all WGs – underscoring both the criticality and the relative scarcity of this expertise within the current membership, and reinforcing the GMP-focused priorities of the policy roadmap (Sections 7.3–7.5).

5.6. Digital infrastructures, data and artificial intelligence

The integration of digital infrastructures, data platforms and artificial intelligence is an emerging yet strategically relevant dimension. National competencies in high-performance computing (HPC), GPU-based workstations, advanced data storage, bioinformatics pipelines and AI-driven image and omics analysis are beginning to support data-driven nanomedicine development, risk assessment and translational decision-making. In the registration survey, AI and computational modeling were classified among the 'strategic/cross-cutting' areas, represented in only 10–25% of declared activities, indicating substantial room for growth and a clear opportunity for the platform to support reproducible, regulatory-compliant digital workflows (Section 6.4).

6. Platform governance: working groups, infrastructure and funding

To translate this mapping into an operational structure, INP adopted a Working-Group-based governance model designed for inclusiveness and cross-disciplinary integration.

6.1. Working groups and organizational model

Eight thematic Working Groups (WGs) were established: Nanotherapeutics and NanoDiagnostics; Regenerative Medicine; Bio/NanoMaterials; Clinical Translation; Preclinical Evaluation and Safety; Physico-chemical Characterization; Regulatory and Industrial Transfer; and Educational and Training. Each WG is coordinated by one Chair, two Vice-Chairs and one Young Spokesperson, ensuring both senior leadership and early-career representation. WG Chair appointments are targeted for completion within the first six months of platform operation (Month 6 milestone: all eight WG Chairs confirmed with signed commitment letters), with each Chair reporting directly to the central coordinating office through quarterly activity reports, annual action plans and defined Key Performance Indicators (KPIs).

Conceptually, the eight WGs are organized into three interconnected macro-platforms (Figure 1): the NanoMed Solutions Platform (Bio/NanoMaterials, Nanotherapeutics and NanoDiagnostics, Regenerative Medicine), focused on the design and engineering of nanomedicine products; the Validation & Quality Platform (Physico-chemical Characterization, Preclinical Evaluation and Safety), providing cross-cutting analytical and biological validation services; and the Translation Platform (Clinical Translation, Regulatory and Industrial Transfer), addressing the pathway to clinical and industrial deployment. The Educational and Training WG operates transversally across all three platforms, reflecting its role as a foundation for human-capital development (Section 6.6).

During registration, participants were asked which Working Groups they would like to join (multiple selections allowed; Table 3). Interest was highest for Nanotherapeutics and NanoDiagnostics and Bio/NanoMaterials, while Regulatory and Industrial Transfer and Clinical Translation received the fewest expressions of interest, mirroring the scientific strengths and translational gaps identified in Section 4.

Participants were also asked about their availability to take on an active coordination role within a WG (e.g., as Chair, Vice-Chair or Young Spokesperson): 41 (29%) indicated 'yes,' 66 (47%) 'possibly, depending on the WG,' and 32 (23%) 'no,' suggesting a substantial pool of candidates from which WG leadership roles can be drawn.

6.2. Research infrastructure network

A key strength identified during the mapping exercise is the breadth of research infrastructure already available across the network. Eight infrastructure clusters were identified, spanning the entire nanomedicine development pathway from nanoparticle production to GMP-oriented scale-up (Table 4).

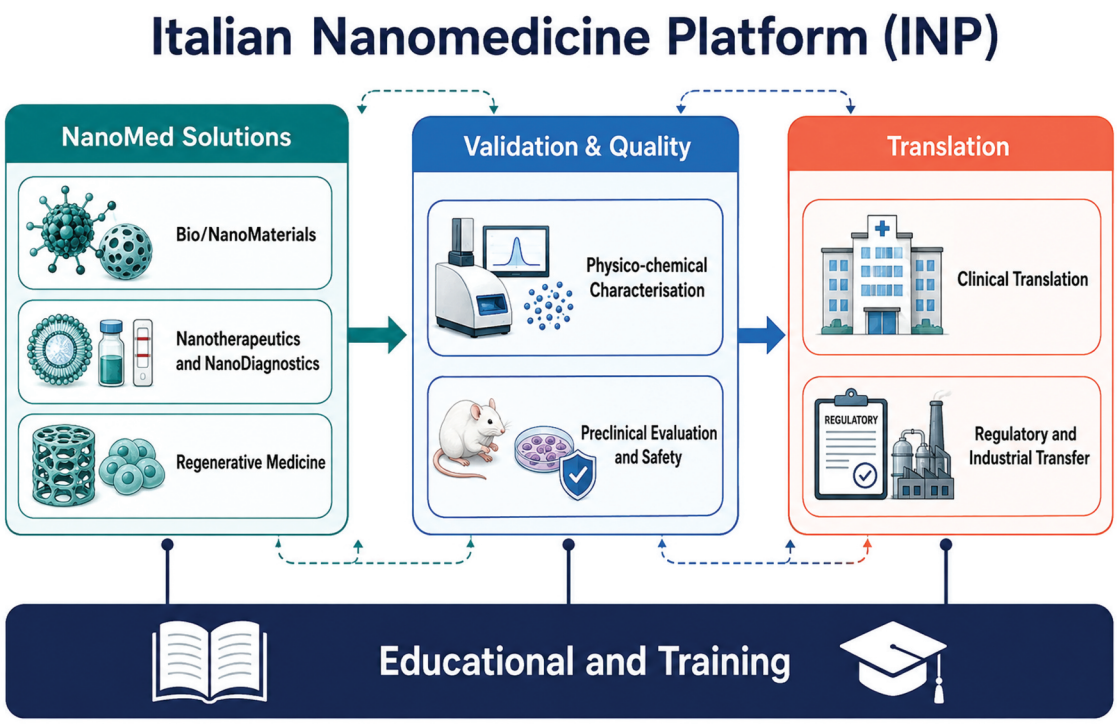


Figure 1. Conceptual organisation of the eight Italian Nanomedicine Platform (INP) Working Groups into the NanoMed Solutions, Validation & Quality and Translation macro-platforms, underpinned by the cross-cutting Educational and Training axis.

Table 3. Expressions of interest in INP Working Groups at registration (multiple selections allowed; $n = 170$ registrants).

Working group	Expressions of interest	Current gaps
Nanotherapeutics and NanoDiagnostics	99	Standardization of nanoparticle characterization protocols
Bio/NanoMaterials	89	Harmonization of biomaterial safety testing across member institutions
Physico-chemical Characterization	67	Lack of shared reference standards and inter-laboratory validation
Preclinical Evaluation and Nanosafety	42	Lack of harmonized SOPs for the preparation, characterization and testing of *in vivo*-ready nanoparticles in clinically-relevant models
Regenerative Medicine	46	Regulatory pathway uncertainties for advanced therapy medicinal products (ATMPs)
Educational and Training	31	Absence of structured national nanomedicine training curricula
Clinical Translation	24	Insufficient industry–academia co-development frameworks
Regulatory and Industrial Transfer	22	Fragmented guidance on nanomedicine-specific CMC and HTA requirements

The 'Current gaps' column shows current enrolment and target membership by Month 12 of INP operation.
Abbreviations: INP: Italian Nanomedicine Platform; WG: Working Group.

Table 4. Research infrastructure clusters mapped across the INP network.

Infrastructure cluster	Strategic added value for the platform
Automated nanoparticle production platforms	Microfluidic systems (e.g., NanoAssemblr, ANP), high-pressure homogenizers, spray dryers, freeze dryers and electrospinning pilot lines, enabling scalable and reproducible nanoformulation development.
Advanced micro/nano fabrication facilities	Clean rooms, soft lithography, 3D printing and bioprinting (FFF, SSE, SLA), and hot-melt extrusion, supporting scaffold/device prototyping and organ-on-chip systems.
Comprehensive physico-chemical characterization suite	DLS, NTA, Zetasizer, SEM, TEM, Cryo-EM, AFM, XRD, SAXS, DSC, TGA, FTIR, Raman and BET, providing full structural, morphological and thermal profiling.
Analytical and mass spectrometry platforms	HPLC/UPLC, LC-MS, MALDI-TOF, ICP-OES and proteomics/metabolomics systems, enabling purity control, compositional analysis and bioanalytical workflows.
Biological and preclinical validation infrastructure	BSL2 cell-culture laboratories (2D/3D), organoids, flow cytometry, CyTOF, single-cell sequencing, animal facilities and *in vivo* imaging systems, supporting end-to-end biological validation.
Advanced imaging and correlative microscopy hubs	Confocal, super-resolution and light-sheet microscopy, AFM-Raman, TERS and electron microscopy platforms, supporting cellular uptake and nano–bio interface tracking.
GMP-oriented and scale-up capabilities	Pilot clean rooms (Class B), sterile formulation units, CMC workflows, analytical QC and lyophilization systems, supporting clinical translation readiness.
Data, HPC and training ecosystem	HPC clusters, GPU workstations, advanced data storage, bioinformatics pipelines, training hubs, biobanks, expert networks and technology-transfer support.

Abbreviations: GMP: Good Manufacturing Practice (GMP); HPC: high-performance computing; INP: Italian Nanomedicine Platform.

Table 5. Funding portfolio across the INP project pipeline, by development stage (Frontier Research; Translational Research; Preclinical & Validation; Industrial Scale-Up; Regulatory/Policy).

Funding type	Frontier	Translational	Preclinical/val.	Scale-up	Regulatory
ERC / Investigator Grants	✓ Strong	◐ Emerging	–	–	–
Horizon Europe (RIA/IA)	✓	✓ Strong	✓ Strong	◐	◐
EIC / Innovation Funding	–	✓	✓	✓ Strong	◐
National Translational Programs	◐	✓	✓ Strong	◐	–
Infrastructure Grants	✓ (enabling)	✓	✓	✓	✓
Policy & Regulatory Calls	–	◐	◐	◐	✓ Strong

✓ present; ◐ emerging/partial; – not represented.
Abbreviations: ERC: European Research Council; EIC: European Innovation Council; RIA: Research and Innovation Action; IA: Innovation Action; INP: Italian Nanomedicine Platform.

6.3. Funding portfolio and active projects

Mapping of active projects across the network shows that INP already covers the entire innovation pipeline, from frontier science to regulatory and clinical integration, supported by a diversified funding portfolio spanning ERC/Investigator Grants, Horizon Europe (RIA/IA), EIC/Innovation Funding, national translational programs, infrastructure grants, and policy/regulatory calls (Table 5). This integrated portfolio combines scientific excellence (strong ERC presence in frontier research), a strong EU collaborative footprint (Horizon Europe RIA/IA spanning frontier through preclinical validation), translational capability (national translational programs, strong at the preclinical/validation stage), industrial scalability (EIC funding, strong at industrial scale-up) and regulatory knowledge (policy and regulatory calls, strong at the regulatory/policy stage).

Regarding the type of collaborations participants are most interested in pursuing through the platform, academic partnerships were by far the most requested (91 responses), followed by industrial (31) and clinical (28) collaborations, with regulatory (7) and educational/training (2) partnerships less frequently prioritized, a distribution that the platform's governance model and roadmap (Section 7) aim explicitly to rebalance, particularly with respect to regulatory and clinical engagement.

7. Policy and innovation vision: a national roadmap for translational nanomedicine

Building on the outcomes of the keynote session, the national pitch session and the registration survey, the First INP Meeting concluded with the presentation of a policy and innovation vision. The Italian Nanomedicine Platform is positioned not only as a scientific coordination body but as a policy-driven innovation infrastructure aimed at transforming national excellence into clinically validated and industrially scalable nanomedicine solutions. This vision integrates governance reform, translational acceleration, regulatory harmonization, industrial competitiveness and European alignment, and is summarized in the following subsections.

7.1. Strategic objectives (5–10-years horizon)

Key long-term objectives include: (i) accelerating translation across TRL 3–6 through standardized preclinical validation pipelines; (ii) strengthening industrial competitiveness via GMP-ready scale-up networks; (iii) aligning national priorities with Horizon Europe Cluster 1; (iv) enhancing regulatory readiness and Health Technology Assessment (HTA) integration; and (v) building interdisciplinary human capital through advanced training programs.

7.2. Governance and operational model

INP proposes a federated governance model supported by a central coordinating office. The eight Working Groups function as operational units with defined Key Performance Indicators (KPIs), annual action plans, and cross-WG integration mechanisms. Rapid-response translational panels are envisioned to provide early regulatory and CMC guidance for emerging nanomedicine projects.

7.3. Funding architecture and economic leverage

A hybrid public–private funding model is proposed, integrating national funds, regional innovation programs, Horizon Europe instruments (including EIC pathways), and industrial co-investment. Dedicated translational bridge funds – estimated at €2–5 million annually from national sources (e.g., MUR and MEF research infrastructure programs), matched by €1–3 million from regional innovation programs (e.g., Programmi Operativi Regionali under EU Cohesion Funds) – would support proof-of-concept clinical pilots and access to GMP scale-up facilities.

7.4. Infrastructure, data and standardisation

The vision includes creating a secure digital infrastructure for data sharing, standardized physico-chemical characterization protocols, harmonization of protein-corona profiling, and mapping of national preclinical and GMP infrastructures. Inter-laboratory validation studies would ensure reproducibility and regulatory compliance across the network mapped in Section 6.2.

7.5. Regulatory alignment and HTA integration

Early dialogue mechanisms with regulatory authorities (e.g., AIFA, ISS) are proposed to support pre-submission scientific advice for nano-enabled therapeutics and devices. Development of a national assay-cascade framework for safety profiling, and alignment with European regulatory guidance, are identified as priorities. Integration of Health Technology Assessment (HTA) principles from early

development stages would enhance reimbursement readiness and economic sustainability, directly addressing the under-representation of regulatory science and HTA noted in Section 4.

7.6. Human capital and training

INP envisions structured PhD and master's programs integrating materials science, pharmaceutical technology, clinical translation and regulatory science. Exchange programs with European partners, and active involvement of early-career researchers within the Working Groups, including the dedicated Young Spokesperson role in each WG (Section 5.2) – are core elements of this strand.

7.7. Key performance indicators and monitoring

Proposed KPIs include: the number of projects progressing from TRL 3–6 to TRL 6–9; the number of coordinated Horizon Europe proposals; the number of multicentre clinical pilots initiated; GMP-enabled scale-up cases; and regulatory submissions supported. Annual monitoring and White Paper updates would ensure adaptive governance and allow the platform to track its progress against the baseline established by the present registration survey.

7.8. 24-month implementation roadmap

- Within 6 months: formalization of governance, activation of the digital platform, and completion of the competency mapping initiated by the registration survey. (Success metric: governance formalized with signed agreements from ≥80% of WG leaders; digital platform operational with ≥100 active registered users.)
- Within 12 months: launch of national characterization ring-studies and publication of the INP White Paper. (Success metric: ≥5 participating laboratories enrolled in the first ring-study; White Paper submitted to a peer-reviewed journal or disseminated as a public policy document.)
- Within 24 months: activation of GMP pilot collaborations and initiation of at least three multicentre translational projects (rare diseases, CNS, oncology), together with coordinated participation in Horizon Europe calls. (Success metric: ≥1 GMP pilot collaboration active; ≥3 multicentre projects initiated; ≥2 Horizon Europe proposals submitted under INP coordination; ≥80 total INP members engaged in WG activities.)

8. Limitations

The findings presented in this report are subject to several limitations. First, the registration survey was conducted during the inaugural round, and the registrant pool may reflect an early-adopter population not fully representative of the broader Italian nanomedicine community. Second, survey data are self-reported and categories such as Technology Readiness Level and collaboration type were not externally verified. Third, Working Group expressions of interest reflect stated intent rather than confirmed participation; actual engagement rates may differ as governance structures mature. Fourth, the absence of a longitudinal baseline limits the ability to assess change over time. Future annual platform surveys will allow systematic tracking of platform growth, WG activity and translational progress against the roadmap milestones defined in Section 7.8.

9. Conclusions: a European-embedded national strategy

The First INP Meeting demonstrated that Italy possesses a nanomedicine ecosystem of exceptional scientific depth, thematic diversity and growing translational maturity. The integrated analysis presented here, combining keynote contributions, a national pitch session and a structured registration survey of 170 participants from 109 institutions, reveals a highly interdisciplinary community with particular strengths in nanocarrier engineering, biomaterials and preclinical validation, alongside structural bottlenecks in GMP scale-up, regulatory harmonization and coordinated clinical translation.

The inclusion of European leadership through ETPN reinforced INP's positioning as a coordinated national node within the European nanomedicine ecosystem, embedded within Horizon Europe Cluster 1 priorities. Without coordinated governance, infrastructure sharing and regulatory alignment, the full societal and industrial impact of this distributed expertise cannot be realized.

In this context, INP is uniquely positioned to act as a national coordinating node: fostering integration across scientific domains, aligning stakeholders along the translational pipeline, and strengthening Italy's contribution to the European nanomedicine landscape. By fostering interdisciplinary integration, supporting GMP and regulatory pathways through its eight Working Groups, and enabling coordinated clinical validation under the 24-month roadmap outlined in Section 6, INP has the potential to accelerate the development of safe, effective and accessible nanomedicine solutions for patients in Italy and across Europe.

A central priority for INP's next phase is to define and operationalize a clear translational pathway from scientific discovery to clinical and industrial deployment. Structured support for the creation of spin-off companies and start-ups emerging from INP Working Groups will be developed through dedicated pre-incubation and mentoring services, connecting academic inventors with technology-transfer offices, venture capital networks and industrial partners. INP will pursue active integration into global nanomedicine networks, including through ETPN's international partnerships with North American, Asian and Australasian platforms, to ensure that Italian innovations reach global markets and that INP members benefit from reciprocal access to international expertise, clinical trial infrastructure and regulatory know-how. Securing sustained governmental support is an equally critical element: INP will engage directly with the Ministry of University and Research (MUR), the Ministry of Health and the National Institute of Health (Istituto Superiore di Sanità, ISS) to advocate for

dedicated translational nanomedicine funding lines, regulatory fast-track mechanisms for nano-enabled therapies, and formal recognition of INP as a national research infrastructure. These actions, combined with the governance, training and standardization initiatives described above, are designed to ensure that the scientific excellence of INP's founding members is systematically converted into therapies, diagnostics and devices that benefit patients in Italy and worldwide.

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Author contributions

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