EFPIA's ONE Vision:
Unlocking Europe's Regulatory Innovation for Faster Patient Access

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EXECUTIVE SUMMARY

To keep pace with advances in science and technology, and the transformation in the way that medicines are discovered, developed, and delivered, the EU must evolve its regulatory model so that innovation reaches patients faster, sustainably, while also maintaining high safety standards.

EFPIA's **ONE Vision** for the future of medicines regulation is a connected, agile, and constantly learning system built on four mutually reinforcing pillars: **One Evidence Lifecycle, One Process, One System, and One Governance**. Together, they form a single, integrated framework where evidence flows seamlessly, knowledge builds cumulatively, and decisions are science-driven, predictable, and trusted.

This evolution goes beyond legislation; it requires adaptive regulatory approaches, coordinated operating models, a forward-looking mindset, and **enhanced digital capability** — all guided by the principles of **simplification, adaptability, and scientific excellence.** Cross-cutting enablers such as data innovation, global collaboration, and policy coherence will ensure the system remains competitive and future-proof.

EFPIA is committed to working with regulators, institutions, patients, and academia to make this **ONE Vision** a reality — ensuring Europe leads the world in regulatory science and delivers innovation faster to every patient.

EFPIA's ONE Vision: Unlocking Europe's Regulatory Innovation for Faster Patient Access

Science and technology are redefining how we discover, develop, and deliver medicines. Artificial intelligence and data-driven methods are beginning to augment every stage of the product lifecycle — from drug discovery and trial design to manufacturing and post-market learning. These tools enable smarter, faster, and more predictive decision-making.

At the same time, innovation is becoming increasingly integrated. New therapeutic modalities such as gene and cell therapies, digital diagnostics, and combined solutions that merge medicinal products with devices or software are transforming the nature of treatment — shifting from chronic management to potential cures and prevention. Patients are already active partners in research and regulatory processes — from co-designing clinical trials to engaging in decision-making — and this role will only continue to strengthen as innovation[1] becomes more personalised and data-driven.

Innovation, however, is outpacing regulation. The European framework — historically strong and science-based — now faces a turning point. To remain globally competitive and to ensure patients benefit from the next wave of innovation, Europe must modernise its regulatory system to reflect the realities of data-driven, AI-enabled, and cross-technology medicinal products and combined solutions.

Together with regulators, patients, and partners, EFPIA proposes a future where scientific excellence, digital capability, and societal trust converge — creating a regulatory ecosystem that accelerates safe innovation, strengthens Europe's competitiveness, and delivers better outcomes for patients.

ONE Vision for the future regulatory framework

The EU needs a well-orchestrated, science-led, and connected regulatory framework that evolves at the pace of innovation — enabling faster, safe access for patients and keeping Europe at the forefront of global regulatory science.

This future framework should deliver coherent, end-to-end oversight across the lifecycle of medicinal products and combined solutions, ensuring that innovation reaches patients swiftly, safely, and sustainably.

By embracing new methodologies, advanced technologies, and a continuum of high-quality evidence, Europe's regulatory environment can empower innovators to deliver care that is increasingly personalised, effective, and accessible, while reinforcing public trust and Europe's global competitiveness in innovation.

[1] Innovation is used generally in this vision to denote a product, medicine, vaccine, diagnostic, alternative therapeutic, cell / gene therapy, treatment, intervention, or a combination of these modalities

Shaping the next generation of global regulatory excellence in Europe

The regulatory system in the EU has a strong foundation, built on scientific rigour, collaboration, and a commitment to patient safety. As innovation evolves, there exists a unique opportunity to modernise the EU's regulatory approach to remain a global leader in science and patient access.

1 Towards an integrated, future-ready oversight model

Europe's regulatory architecture has served patients well for decades, but it was not designed for today's cross-technology landscape. By strengthening connections between pathways for medicinal products, devices, diagnostics, and digital health, the EU can create a more integrated, agile system. A clearer governance model and structured collaboration across authorities would reduce duplication, enable faster decisions, and deliver more predictable outcomes across the product lifecycle – from early scientific advice to post-authorisation use.

2 Building agility to enhance global competitiveness

Scientific innovation moves fast – and Europe can continue to lead by evolving its regulatory processes to match that pace. Learning from best practices in other regions which have adopted more flexible and adaptive regulatory models, Europe has the opportunity to strengthen its own agility. By embracing similarly risk-based and iterative approaches, Europe can ensure that patients benefit from innovation at the same speed as their peers worldwide. Modernising processes will enhance Europe's attractiveness for investment, stimulate cutting-edge research and reinforce its position as a global leader in health innovation.

3 Strengthening regulatory science and expertise

Europe's regulatory network already hosts exceptional expertise. Connecting knowledge across institutions and development stages will help ensure that insights gained during early advice and clinical trial applications carry forward into later phases. At the same time, investing in emerging areas such as artificial intelligence, advanced manufacturing, data analytics and with the strategic use of regulatory sandboxes, the EU will build a dynamic, learning regulatory ecosystem.

4 Ensuring sustainable capacity and resourcing

Maintaining excellence in the face of growing complexity requires new ways of working. By investing in sustainable resourcing and deepening collaboration across national agencies and European institutions, the EU can build a resilient, high-performing regulatory network. This will support timely decision-making, quality assessments, and the efficient management of increasingly complex evidence and technology landscapes – ensuring that innovation translates more swiftly into patient benefit.

5 Fostering coherence across policy frameworks

The EU's medicines regulation framework interacts with a broad range of policy areas, from chemicals and the environment[2] to digital governance and health technology assessment. Strengthening alignment among these frameworks offers an opportunity to build coherence, reduce duplication, and enhance predictability for innovators. Early coordination – for instance between the AI Act, the European Health Data Space, environmental legislation, and medical devices regulation – can ensure that policy goals reinforce one another, supporting both efficiency and innovation.

[2] https://www.efpia.eu/media/i0ihfkys/efpia-cumulative-legislative-impacts.pdf

A shared vision for a modern, learning regulatory system

Together, these opportunities point to a single goal: a modernised, constantly learning regulatory system that keeps pace with science, fosters collaboration, and delivers faster, more equitable access for patients. By embracing this evolution, Europe can reinforce its scientific leadership, attract global investment, and ensure that innovation continues to reach those who need it most.

Future EU Regulatory Framework

EFPIA's **ONE Vision** sets out a roadmap for a connected, agile, and learning regulatory system — built on four pillars:

Together, these pillars aim to transform Europe's regulatory framework into a fully integrated, science-led model that accelerates both innovation and patient access.

This transformation goes beyond legislation, requiring adaptive regulatory approaches, coordinated operating models, a forward-looking regulatory mindset, and enhanced digital capability across the network. It should be guided by the principles of **simplification, adaptability, and scientific excellence** — ensuring that regulatory evolution remains both effective and future-proof.

Delivering the **ONE Vision** will depend on cross-cutting enablers — including **digital transformation, effective data use, global collaboration, and policy coherence** — that strengthen every stage of the regulatory lifecycle.

One Evidence Lifecycle

From: Fragmented, one-off evidence packages assessed in isolation at fixed points in time.

To: A connected, living evidence ecosystem where all data sources — from pre-clinical and clinical research to real-world use — continuously inform regulatory decisions.

The current regulatory framework relies on separate, often duplicative evidence packages prepared for different milestones — scientific advice, clinical trials, and marketing authorisation — each assessed in isolation. The future must deliver a connected evidence ecosystem, where *all relevant data sources* are progressively built, shared, and reused across the lifecycle.

This means integrating pre-clinical and clinical trial evidence with complementary evidence from clinical practice — including real-world data (such as that from registries), academic research, and patient-generated insights. Together, these sources form a continuous evidence flow that strengthens regulatory decision-making at every stage.

Instead of static submissions, Europe should move toward a "living evidence lifecycle" — where knowledge evolves in real time, enabling all trial designs, iterative engagements with regulators and assessments, and cumulative understanding of benefit and risk. To make this possible, Europe must ensure data quality, interoperability, and governance frameworks that build trust and scientific integrity.

What Europe Needs to Achieve It:

To realise EFPIA's **ONE Vision**, Europe must develop the capability to integrate and interpret all relevant evidence — wherever it originates — within a single, connected regulatory continuum. This requires progress in four key areas:

1

Regulatory Evidence Interoperability

Harmonise methodologies, data standards, and evidence requirements to enable the reuse of data from diverse sources — including clinical trials, real-world data, registries, and public–private data infrastructures. Interoperability will allow cumulative learning, reduce duplication, and increase regulatory efficiency.

2

Digital infrastructure

Build secure, interoperable digital platforms that enable regulators to access, exchange, and analyse both sponsor-generated and external data in near real time. The European Health Data Space (EHDS) will provide a legal and technical framework for the cross-border access and secondary use of electronic health data and should interconnect seamlessly with regulatory systems. In parallel, other data sharing platforms can serve as federated networks generating evidence to inform regulatory decision-making across the product lifecycle.

3

Lifecycle scientific dialogue

Foster continuous, structured interaction between regulators, developers, notified bodies, academia, and data holders throughout all stages of development — from early R&D to post-authorisation learning. Early and ongoing dialogue should ensure that evidence from diverse sources is jointly discussed, accepted, and

integrated as it emerges, supporting a shared and cumulative understanding of benefit and risk.

4

Governance and Sustainable Collaboration

Embed collaborative structures and oversight models that promote transparency, early data sharing, and co-creation of evidence. Regulatory frameworks should reward responsible data contribution and sustained knowledge exchange between all actors. Examples include dedicated regulatory stewards (see below – *One Process*) who ensure continuity across development stages, and multi-stakeholder evidence platforms that bring together regulators, HTA bodies, academia, and developers to align methods and standards. Governance frameworks should also provide trusted mechanisms for data sharing and joint capacity building, rewarding sustained collaboration and collective learning across the system.

Why It Matters: It enables faster, more informed decisions, reduces duplication, and ensures that every new data point — from clinical research to real-world use — contributes to a shared, evolving understanding of benefit and risk.

One Process

From: Disconnected procedures and sequential regulatory steps across scientific advice, clinical development, manufacturing, and assessment.

To: An integrated, adaptive, end-to-end regulatory process for all medicinal products and combined products, enabling continuous knowledge building, iterative assessment, and agile interaction between developers and regulators.

Today's regulatory pathways remain fragmented and procedural, often moving step by step through fixed milestones and disconnected scientific dialogues. This approach slows the pace of innovation and limits opportunities to apply emerging evidence or learning across the lifecycle.

The future should deliver an adaptive, integrated process that connects early development, clinical research, MA assessment, manufacturing, and post-authorisation oversight within a single continuum. Crucially, this must apply not only to medicinal products, but also to combined products that bring together medicines, devices, diagnostics, and digital tools within one therapeutic concept.

Scientific dialogue and regulatory evaluation should evolve together — allowing data, insights, and decisions to build cumulatively rather than restart at each stage. Such an approach would enable more predictable, science-based decisions and foster agile, collaborative interaction between developers and regulators, ensuring that innovative treatments and integrated solutions reach patients faster while maintaining confidence in their quality, safety, and efficacy.

What Europe Needs to Achieve It:

To realise EFPIA's **ONE Vision**, Europe must move from a sequential, milestone-based system to a connected, learning process that enables real-time interaction and continuous assessment. This requires several key shifts:

1 A Single-Entry Point for Scientific and Regulatory Interaction

Create a unified access point for all scientific and procedural interactions, coordinating advice, early dialogue, and guidance across the network for medicinal products and combined products. This single-entry point would simplify engagement, reduce administrative burden, and ensure consistent expectations from early development to authorisation and post-market phases. It would enable continuous, cumulative dialogue with a stable core of experts, ensuring that insights carry forward across stages and support coherent oversight across interconnected frameworks.

2 Lifecycle Regulatory Stewardship for Knowledge Continuity

Introduce a Lifecycle Regulatory Steward — a dedicated regulatory contact or team that follows a product or technology platform throughout its development and post-authorisation phases. The steward would ensure continuity of knowledge, preserve scientific understanding, and maintain a clear line of communication between regulators and developers. By carrying institutional memory across stages and coordinating input from scientific, quality, and clinical experts, this approach would strengthen predictability, efficiency, and trust across the entire regulatory process.

3 Iterative and Connected Scientific Advice

Transform scientific advice from a single milestone into an ongoing, iterative process that evolves alongside evidence generation. Developers and regulators should engage in dynamic, connected dialogues where data and insights are reviewed as they emerge, enabling continuous refinement of development strategies. A core group of experts – including Lifecycle Regulatory Steward - should accompany each product or technology across stages, ensuring consistency, cumulative learning, and predictable, science-based decision-making.

4 EU Priority Designation for Transformative Innovation

Establish an EU Priority Designation to accelerate the evaluation of products that address unmet medical needs, demonstrate transformative potential, or are of strategic importance. Building on existing expedited pathways, this designation should provide a structured, time-bound, yet flexible framework that enables real-time interaction, dynamic data review, and adaptive assessment. Supported by strong scientific coordination across the EU network, it would ensure that innovations of greatest public-health and societal value reach patients earlier while maintaining rigorous standards of quality, safety, and efficacy.

5 Integration of Clinical Research with Development and Assessment

Strengthen the connection between clinical research, scientific advice, and regulatory evaluation to overcome fragmentation and duplication in their review. Evidence generated through pre-clinical and clinical studies should feed directly into ongoing regulatory dialogue and assessment via a core dossier model, allowing emerging data to inform decisions earlier. A more coordinated model for clinical trial applications, coordinated by the EMA, is particularly necessary for

multi-country trials, ensuring predictability, consistent governance, harmonised evaluation standards, and efficient oversight across medicinal products and combined products. Such coordination will enable smoother evidence generation and faster translation of research into patient access.

6 Modern Manufacturing and Quality Oversight

Develop a regulatory framework that balances robust oversight with the flexibility needed to drive innovation in manufacturing and quality control. Oversight should facilitate the adoption of new technologies — such as continuous, decentralised, or point-of-care manufacturing and AI-supported process monitoring — while maintaining the highest standards of safety, reliability, and product quality.

Integrating sustainability objectives into manufacturing innovation is essential: new technologies can enable cleaner, more efficient processes that reduce resource use and waste, supporting EU climate goals without compromising quality or patient access[3].

A platform-based regulatory approach should allow validated processes and technologies to be applied across multiple products or families, creating efficiencies and accelerating scale-up. The EMA, through a strengthened Quality Innovation Group (QIG) and coordinated network of expertise, should guide and harmonise these innovations across the EU, promoting consistent implementation, efficient oversight, and faster translation of technological advances into improved patient access and supply resilience.

7 Post-Authorisation Efficiency and Proportionality

Modernise the variations framework to make post-authorisation oversight more adaptive, proportionate, and data driven. Regulatory resources should be focused where oversight delivers the greatest value — on changes with a real impact on quality, safety, or efficacy — while routine or low-risk variations follow simplified, faster procedures.

Digital tools, advanced analytics, and data access should support dynamic lifecycle management, enabling proactive updates of validated information and reducing unnecessary administrative steps. This evolution would free regulatory capacity, enhance agility, and keep oversight both rigorous and responsive to scientific progress.

8 Smarter, Dynamic Risk Minimisation

Evolve risk minimisation into a flexible, evidence-based process that adapts as new data emerge. Current practices often accumulate measures over time, making it difficult to phase out those that are no longer effective or proportionate. A more dynamic approach — informed by real-world evidence, post-authorisation data, and ongoing benefit–risk evaluation — should enable measures to be adjusted, simplified, or discontinued as appropriate, strengthening patient safety and reducing unnecessary complexity.

Why It Matters: An adaptive, connected regulatory process will shorten timelines, strengthen predictability, and ensure scientific continuity — allowing innovation to move at the pace of science and bring new treatments to patients faster, while maintaining Europe's high standards of safety and quality.

[3] https://www.efpia.eu/media/pt5fa401/efpia-sustainability-proposal-to-medicine-regulators.pdf

One System

From: Fragmented digital tools and static dossier submissions.

To: A connected, interoperable digital ecosystem that supports seamless data flow, real-time collaboration, and end-to-end oversight across the product lifecycle.

The EU's future regulatory framework must be underpinned by modern, connected digital systems that support every stage of the product lifecycle. Europe should evolve from static, document-based submissions toward a data-driven, cloud-enabled environment where evidence can be securely accessed, shared, and assessed in real time.

A single-entry point for applicants — combined with integrated reviewer access — should enable information to follow the principle of "enter once, use many times." Such an ecosystem would connect scientific advice, clinical trials, manufacturing, and post-authorisation data within a secure, interoperable infrastructure, enabling true end-to-end oversight, avoiding duplication, and supporting smarter, faster regulatory decisions.

What Europe Needs to Achieve It:

To realise EFPIA's **ONE Vision**, Europe must move from fragmented tools to a unified, interoperable digital backbone that connects all actors and systems in the regulatory network. This requires progress in several key areas:

1 Cloud-Based Regulatory Platforms

Transition from file-based submissions to secure, cloud-based platforms that enable dynamic data exchange and collaborative review. This approach would allow regulators to access up-to-date information throughout development, facilitating dynamic assessments, improving coordination, and reducing administrative complexity.

2 Common Data Models and Standards

Implement stable, well-governed data models and interoperability standards across all regulatory systems — including product, organisation, and manufacturing data — to ensure coherence and predictability. Clear versioning and transparent change management will help regulators and developers plan with confidence and ensure long-term system stability.

3 Integration Across Systems and Processes

Create structured connections between core platforms allowing validated data to be reused across processes without re-entry. Legacy systems should be progressively decommissioned through a coordinated transition plan, enabling a streamlined, single digital environment that supports full lifecycle management.

4 Single EU Portal for Submissions and Communication

Complementing the single-entry point for scientific and procedural dialogue described in One Process, Europe also needs a single digital environment for all regulatory submissions and communications. This EU-wide portal would serve as

the technical interface connecting applicants and regulators across all procedures and lifecycle activities for medicinal products and combined solutions.

By replacing today's multiple portals and fragmented tools, it would enable two-way communication, real-time data exchange, and transparent tracking of progress throughout the regulatory process. This integrated platform would ensure that information moves seamlessly alongside scientific dialogue — creating full alignment between procedural and digital pathways.

5 **Smart Governance and Shared Accountability**

Co-create a coordinated governance model that ensures transparency and predictability. The EMA, supported by Member States, should act as the central orchestrator of this digital ecosystem —harmonising system functionality, and maintaining oversight of digital standards and data governance.

Why It Matters: A connected, interoperable regulatory system will cut duplication, speed up decision-making, and ensure that reliable, up-to-date data supports every stage of development — enabling smarter, faster, and more consistent regulation across Europe while conserving resources and reducing unnecessary burden.

One Governance

From: A fragmented and decentralised regulatory network with dispersed expertise and limited coordination.

To: A single, strategically orchestrated system led by an empowered EMA that integrates and leverages Member State expertise, ensuring unified scientific leadership, coherence, and consistency across the EU.

The future regulatory system should be built around a single orchestrating agency, transforming the EMA into an empowered scientific authority with ownership of scientific assessment and regulatory decision-making across the EU framework. The agency should take a proactive, strategic role in planning, directing, and coordinating complex regulatory activities, ensuring coherence, quality and agility across the system.

This model would strengthen—not replace—the European regulatory network. Member States' authorities will remain central to the system, contributing their scientific expertise and operational capacity through a coordinated, collaborative review structure. The EMA should act as the strategic hub, guiding and integrating this sustainable network of excellence so that competent authorities, notified bodies, and ethics committees work together as one.

Such a structure would ensure consistency across human medicinal products and combined products, providing stronger leadership for a harmonised, efficient, and future-proof regulatory landscape. Ensuring continuity across the full product lifecycle, while pooling scientific knowledge across therapeutic areas and disciplines such as clinical trials and manufacturing, would enable informed, evidence-based decisions and make optimal use of Europe's collective expertise. Institutional knowledge and regulatory experience should be treated as a shared EU resource, built cumulatively through coordinated knowledge management and proactive monitoring of emerging science and technology.

What Europe Needs to Achieve It:

Delivering EFPIA's **ONE Vision** requires clear mandates, coordinated structures, and sustainable investment that enable the EMA and Member States to act as one network. Europe must modernise its governance model to combine central scientific leadership with shared accountability and expertise across the regulatory system.

1 Redefine the EMA Mandate: Scientific Leadership and Agile Decision Making

Empower the EMA to take full ownership of scientific assessment and regulatory decision-making across the lifecycle, shifting its focus to proactive scientific coordination and quality assurance. This should include faster, more coherent decision-making, stronger foresight on emerging technologies, and greater capacity for data-driven evaluation. The Agency's leadership must go hand in hand with a strengthened role for national authorities, ensuring that Member State expertise continues to underpin assessments and inform decisions.

- **Scientific and Agile Focus:** Redirect EMA resources toward anticipatory regulatory science and early engagement on new methodologies and data use.
- **Unified Scientific Assessment Ownership:** Empower EMA to lead the scientific assessment across all critical stages of development, ensuring quality, consistency and continuity.
- **Regulatory Decision Ownership:** Allow the EMA Executive Director to adopt final decisions on marketing authorisations, safety changes, and dispute resolutions following CHMP opinion with appropriate guardrails — supported by a transparent mechanism for Member State input and oversight to ensure shared accountability and trust.
- **Revitalise the CHMP:** Ensure the CHMP is a vibrant forum for strategic scientific debate and regulatory innovation, dedicating less time to procedural management and more to advancing regulatory science.

2 Forging a Pan-European Network of Scientific Excellence

The effectiveness of Europe's regulatory system depends on its ability to access and mobilise the best available scientific knowledge. A modern governance model should formalise and strengthen the network of expertise across the EU — enabling the EMA to consistently draw on top-tier specialists from Member States, academia, and other expert institutions. This structure will reinforce quality, speed, and scientific depth in assessments while maintaining a truly European system that leverages collective excellence.

- **Virtual Centres of Excellence:** Establish flexible, thematic Centres of Excellence across key therapeutic areas and disciplines. These centres should connect experts from regulatory agencies, academia, notified bodies, and European reference networks to provide coordinated, high-quality input to regulatory decision-making.
- I**ncentivise Member State Contribution:** Recognise that Member States remain the backbone of Europe's scientific expertise and there is a need for them to be incentivised to invest in regulatory science and sustain excellence in their national systems thus retaining influence on the EU regulatory framework.
- **Internalise Core Competences:** Build and maintain in-house EMA expertise in strategically critical areas such as data analytics, AI, and manufacturing/

quality oversight eliminating structural dependencies without fragmenting the system. Strengthening these internal competences will improve continuity, and ensure the EMA remains a global leader in regulatory science. To ensure timely access to the right skills, the EMA should also contract experts directly when needed.

3 Ensure Accountability through Transparent Oversight

As decision-making becomes more centralised, maintaining trust, legitimacy, and transparency will be essential. Effective governance is not only about who decides, but also how those decisions are understood and trusted. Member States must retain a formal role in overseeing how decisions are made and implemented, ensuring that the EMA's actions remain aligned with public-health priorities and reflect Europe's shared values. Oversight mechanisms should be strategic and light-touch — providing assurance without adding bureaucracy or slowing innovation.

- **Shared Oversight Mechanism:** Retain a structured framework that provides Member States with oversight of EMA decisions, ensuring visibility, trust, and alignment with public-health needs. Oversight must be robust yet proportionate, safeguarding accountability while maintaining agility and scientific focus across the system.
- **Transparency and Reporting:** Reinforce confidence by publishing clear rationales for major regulatory decisions and communicating outcomes in a timely, accessible manner.

4 Build Sustainable Capability and Resources

Delivering a future-ready regulatory system requires sustained investment in people, skills, and infrastructure. Both the EMA and Member States need stable, predictable resources to develop expertise in emerging science, data, and technology. Strengthening capability across the network will ensure that Europe can adapt, innovate, and remain a global leader in regulatory science.

- **Dedicated, Transparent Funding Streams:** Secure long-term, ringfenced investment for capability building — including expert training, recruitment of specialists, and modernisation of digital and data systems. Establish a mechanism to identify priorities jointly with stakeholders.
- **Continuous Learning and Exchange:** Foster a culture of learning and collaboration through cross-network training, knowledge exchange, and mobility programmes that build shared competence and consistency.
- **Future-Proof Systems:** Invest in advanced data and digital infrastructures across the network to support evidence-driven, efficient, and resilient regulation that keeps pace with scientific progress.

Why It Matters: Stronger, coordinated governance will make regulation faster, more consistent, and trusted — ensuring Europe remains a global leader in science-based decision-making.

Opportunities for European Regulatory Leadership

Delivering EFPIA's **ONE Vision** – *One Evidence lifecycle, One Process, One System, One Governance* – means evolving from fragmentation to full integration across the product lifecycle; a regulatory framework that is connected, data-driven, and science-led, where evidence flows seamlessly, knowledge and decisions build cumulatively, and governance ensures coherence and accountability.

Europe's Leadership Opportunity in Regulatory Science

Europe has the expertise, institutions, and credibility to lead the next generation of regulatory science. By leveraging its scientific foundations, the EMA and its network can shape a globally recognised model of regulatory excellence — one that is agile, transparent, and centred on patient benefit.

Embedding regulatory sandboxes as a standard practice, alongside adaptive assessment models, data-driven approaches, and the responsible use of AI, will continuously modernise the EU regulatory framework and ensure it can effectively oversee future innovation. Through this, Europe can set global benchmarks for evidence-based, agile decision-making that both protects public health and defines what excellence in regulatory science looks like in the digital era.

Delivering on EFPIA's **ONE Vision** must be matched with measurable impact. Progress should be tracked through shared indicators — such as faster time-to-decision, greater data interoperability, stronger knowledge continuity, and improved patient access — developed collaboratively with stakeholders to ensure accountability, transparency, and continuous learning across the system.

Convergence and Reliance

Europe's influence extends beyond its borders through cooperation and shared trust. Strengthening collaboration and spearheading innovative initiatives within global organisations such as ICH, ICMRA, and WHO platforms can promote mutual reliance and convergence — helping to accelerate access to innovation and build confidence in European assessments. Reliance mechanisms, especially those led by the EMA, can become powerful tools to support faster, globally recognised evaluations and improve access to essential medicines across regions.

Innovation as a Competitive Advantage

Europe's world-class science and academic expertise are among its greatest strengths. By combining regulatory agility with this foundation and strong public–private partnerships – such as the Innovative Health Initiative (IHI) – Europe can create environments that encourage experimentation, data sharing, and collaborative problem-solving. Policies that provide safe harbours for pre-competitive research and early stakeholder dialogue will reinforce Europe's position as a hub for cutting-edge innovation that benefits both patients and society.

EFPIA is committed to working with institutions, regulators, patients, and academia to turn their ONE Vision into reality – ensuring Europe remains a global leader in regulatory science and delivers innovation faster to every patient.