



INTEGRATED REPORT

20
24

TABLE OF CONTENTS

| | |
|--|-----------|
| LETTER TO STAKEHOLDERS | 2 |
| ABOUT THIS REPORT - METHODOLOGICAL NOTE | 3 |
| HIGHLIGHTS | 4 |
| ORGANIZATIONAL OVERVIEW | 5 |
| SERVICES OFFERED “FROM RESEARCH TO MARKET” | 9 |
| GOVERNANCE | 16 |
| BUSINESS MODEL AND STRATEGY | 19 |
| RISK MANAGEMENT | 22 |
| STAKEHOLDER ENGAGEMENT | 25 |
| OUR STRATEGIC BLUEPRINT | 28 |
| PERFORMANCE 2024 | 31 |
| OUTLOOK - 2025 | 36 |

LETTER TO STAKEHOLDERS

I am proud to present the 2024 Integrated Report for Regulatory Pharma Net (RPN). Following the foundational organizational transformation we completed in 2023, the year 2024 was defined by strategic execution and tangible growth. It was a year where our renewed structure proved its strength, allowing us to navigate a complex global landscape with greater agility and to deliver value to our clients and partners.

Everything we achieved in 2024 is rooted in our corporate philosophy. Our commitment to dedication, integrity, and excellence guided every action as we successfully translated the potential of our new organization into the measurable results you will find throughout this report.

The organizational enhancements of 2023 were designed to improve our cohesion and innovation, and in 2024, we reaped the rewards. This is demonstrated most clearly by a significant increase in our revenues, a direct result of our focused strategy and collective effort. Our revitalized structure empowered us to act decisively on our growth ambitions, with a sharpened focus on business development activities to drive client acquisition and market expansion.

Our vision of success transcends financial performance, embracing our role as a transparent and responsible corporate citizen. We are therefore proud to have obtained in 2024 the Legal Rating: an important recognition that affirms our ongoing commitment to compliance, integrity, and ethical business conduct. This achievement reinforces our dedication to generating value that is both economically sound and aligned with the principles of good governance.

At RPN, our success is driven by our people. Our commitment to fostering an equitable and inclusive work environment was formally recognized in 2024 with the obtaining of the Gender Equality Certification. This significant achievement complements our substantial investments in the internal development of our resources and our culture, where we launched targeted programs to ensure our team remains at the cutting edge.

To better reflect our forward-thinking identity, 2024 also marked a milestone for our brand: we successfully reshaped our logo and launched a new, dynamic website. This renewed digital presence is a vital tool for deepening engagement with our clients and partners. To highlight our ability to deliver fully integrated services, we added the payoff “Life Science Solution” to our historic name: a clear statement of our commitment to providing comprehensive, end-to-end support across every stage of the journey.

The new logo retains the familiar RPN initials, now enclosed within a square - a symbol of unity made up of diverse souls - representing a single, cohesive entity shaped by multiple dimensions of expertise and passion.

As we look to 2025, our mission is clear. The comprehensive development plan we shaped in 2024 provides a strategic roadmap for the years ahead. It will guide our efforts as we leverage our strong foundation to anticipate future trends and continue to innovate our services.

We sincerely thank you-our clients, partners, and dedicated employees-for your continued trust and support. Your collaboration is vital to our shared success.

*CEO & Founder
Anita Falezza*

ABOUT THIS REPORT

METHODOLOGICAL NOTE

Regulatory Pharma Net Srl (RPN) voluntarily publishes its 2024 Integrated Report to offer a transparent account of our value creation journey. This document is crafted for all our stakeholders—including employees, clients, suppliers, and partners—to provide key insights into our performance and strategy.

This report is prepared in accordance with the International <IR> Framework (updated January 2021) to ensure it meets global best practices. Our disclosures are guided by the GRI Standards 2021 and align with key non-financial reporting regulations, including the Italian Legislative Decree 254/2016 and the principles of the EU's Corporate Sustainability Reporting Directive (CSRD).

Through this report, RPN reinforces its accountability and strategic positioning for future opportunities. It highlights our dedication to sustainable growth, innovation, and corporate responsibility, underpinning our long-term vision.

Purpose of the Integrated Report

The purpose of this Integrated Report is to offer a holistic view of RPN's financial and non-financial performance. The content is focused on the material topics most relevant to our business and stakeholders, identified through a careful analysis of:

- Factors critical to our strategic success
- Key risks identified via our comprehensive risk management framework
- Direct feedback and insights gathered from our stakeholders.

This report covers RPN's activities for the fiscal year 2024 (from January 1st to December 31st).

Source of Information

The information and data within this report are compiled from reliable internal sources, including:

- Company management and accounting systems
- Findings from our stakeholder engagement initiatives
- The company-wide risk assessment process.

By integrating these sources, we provide a transparent and cohesive narrative of how RPN creates sustainable value.

HIGHLIGHTS

| | |
|---|--|
|  <p>Equity 100%</p> |  <p>Net Financial Position 11.000.000 €</p> |
| <p>Turnover more than 6.300.000 €</p>  | <p>Value distributed to stakeholders more than 5.000.000 €</p>  |
| <p>Number of clients more than 140</p>  |  <p>Loyalty rate 80%</p> |
|  <p>Quality Management System Certification ISO 9001:2015 and ISO 27001:2022</p> | <p>Average training hours per employee approx 100</p>  |
| <p>Customer satisfaction 3.5 / 4</p>  | <p>Qualified Suppliers 100%</p>  |

ORGANIZATIONAL OVERVIEW



CORPORATE IDENTITY

- Since our founding in Italy in 1999, Regulatory Pharma Net (RPN) has become a leading international service provider in the Life Sciences sector. Our key differentiator is our global expertise, enabling us to navigate complex regulatory landscapes and manage projects involving major bodies like the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).
- Our unwavering commitment to quality and responsible business practices is certified by UNI EN ISO 9001:2015, ISO 27001:2022, and UNI/PdR 125:2022 for gender equality. Furthermore we obtained the Italian Legality Rating, issued by the Autorità Garante della Concorrenza e del Mercato (AGCM), further affirming our ethical conduct, transparency, and compliance with national regulations.
- Our rebranding in 2024 marked a significant step forward by adding “Life Science Solution” to our historic name and reshaping our visual identity, we underscored our capacity to deliver integrated, end-to-end services across the entire product lifecycle.
- Today, RPN stands as a strategic partner for companies in the Life Sciences industry offering seamless support from early development and regulatory approval to market access and post-launch success.
- By blending a global vision with deep local expertise, we continue to empower our clients to thrive in the ever-evolving life sciences landscape.

CORE VALUES

Our values are the living expression of who we are: the essence of RPN. They reflect our identity and guide every action, partnership, and innovation as we deliver integrated solutions across the life sciences ecosystem.

- **Commitment**
We approach every project with precision, accountability, and a deep sense of purpose. Our dedication to excellence ensures that every solution we deliver is robust, reliable, and client-focused.
- **Integrity**
We believe that trust is built through transparency and ethical conduct. Integrity defines how we collaborate with clients, partners, and colleagues, to achieve meaningful and sustainable outcomes.
- **Dynamism**
In a fast-changing industry, agility is key. We embrace change with energy and adaptability, turning complexity into opportunity and keeping our clients ahead in competitive markets.
- **Collaboration**
We work side by side with our clients as one team. Through open dialogue and shared vision, we co-create tailored strategies that align expertise, ambition, and measurable results.
- **Insightful Thinking**
Our experience meets critical thinking. By blending strategic vision with analytical depth, we anticipate challenges and design solutions that accelerate innovation.
- **Excellence**
Excellence is not a goal, it's our standard. It drives the quality of our work, the professionalism of our people, and the impact of the results we deliver every day.

Together, these values define RPN a unified organization made of diverse strengths, driven by purpose, and committed to shaping the future of Life Sciences through integration, innovation, and trust.

SUSTAINABLE DEVELOPMENT GOALS 2030: A GLOBAL SHIFT IS UNDERWAY

At RPN, we view the United Nations' 2030 Agenda for Sustainable Development as a vital framework for our corporate strategy. We believe that long-term success is intrinsically linked to creating value not only for our business but for society and the planet.

Rather than addressing all 17 goals, we have strategically focused our efforts on the seven Sustainable Development Goals (SDGs) where we can make the most significant and direct impact. Our selection is guided by our core mission in the Life Sciences industry, our operational practices, and our commitment to our people.

Our contributions are focused on the following areas:

CORE MISSION & INDUSTRY IMPACT

SDG 3: Good Health and Well-being

This goal lies at the very heart of our purpose. Every day, through our integrated regulatory, scientific, and strategic services, we empower our clients to develop and deliver safe, effective, and innovative healthcare products. By supporting the entire product lifecycle—from development to market access—we contribute directly to advancing global health and patient well-being

SDG 9: Industry, Innovation, and Infrastructure

Through our expertise in regulation, quality, and market access, we play an active role in strengthening the healthcare ecosystem. We help build resilient and innovative industry infrastructures, ensuring that breakthrough technologies and treatments can reach patients efficiently, safely, and sustainably.

OUR PEOPLE & WORKPLACE

SDG 5: Gender Equality

At RPN, gender equality is not only a social responsibility, it is a defining part of who we are. Diversity, inclusion, and equal opportunity are the foundations of our culture and an essential driver of our long-term growth.

In 2024, our commitment was formally recognized through the achievement of the UNI/PdR 125:2022 Gender Equality Certification, confirming that equity and inclusiveness are embedded in every aspect of our organization, from recruitment and career development to leadership and decision-making. We believe that empowering women and fostering balanced representation strengthens creativity, collaboration, and performance.

SDG 8: Decent Work and Economic Growth

We strive to be an employer of choice by providing stable, high-quality employment and fostering an environment where every individual can grow and contribute meaningfully. At RPN, we see our people as an integral part of the same ecosystem of integration that defines our services, where diverse skills, perspectives, and experiences connect to generate collective value.

By investing in continuous learning and professional development, we nurture talent and empower our teams to evolve alongside the dynamic Life Sciences landscape. This integrated approach ensures that our people thrive, driving sustainable growth for both our organization and the communities we serve.

SDG 4: Quality Education

We are dedicated to lifelong learning and advanced professional development, ensuring that our people remain leaders in their fields and continue to evolve with the rapidly changing Life Sciences landscape.

This commitment to knowledge is part of our integrated approach: by connecting diverse skills and experiences, we create a dynamic ecosystem where learning flows across teams, projects, and disciplines.

The result is a culture of excellence, innovation, and knowledge-sharing that strengthens not only our organization but also the clients and partners we serve, amplifying impact across the entire healthcare value chain.

RESPONSIBLE OPERATIONS

SDG 12: Responsible Consumption and Production

At RPN, sustainability is an integral part of our identity and operational strategy.

We are committed to continuously enhancing our operational efficiency to minimize our environmental footprint, from responsible resource management and waste reduction to promoting sustainable practices across our offices and supply chain.

Our integrated approach to sustainability reflects the same philosophy that drives our services: connecting every element of our organization to create lasting, measurable value.

Building on this foundation, we have set a new goal for 2025: to achieve the EcoVadis sustainability certification, further validating our commitment to responsible business practices and continuous improvement.

SDG 16: Peace, Justice, and Strong Institutions

Integrity is one of the cornerstones of RPN. It guides how we operate, how we collaborate, and how we contribute to shaping a more transparent and responsible Life Sciences ecosystem.

We uphold the highest ethical standards in every aspect of our business and support our clients in navigating complex regulatory and compliance frameworks with clarity and accountability.

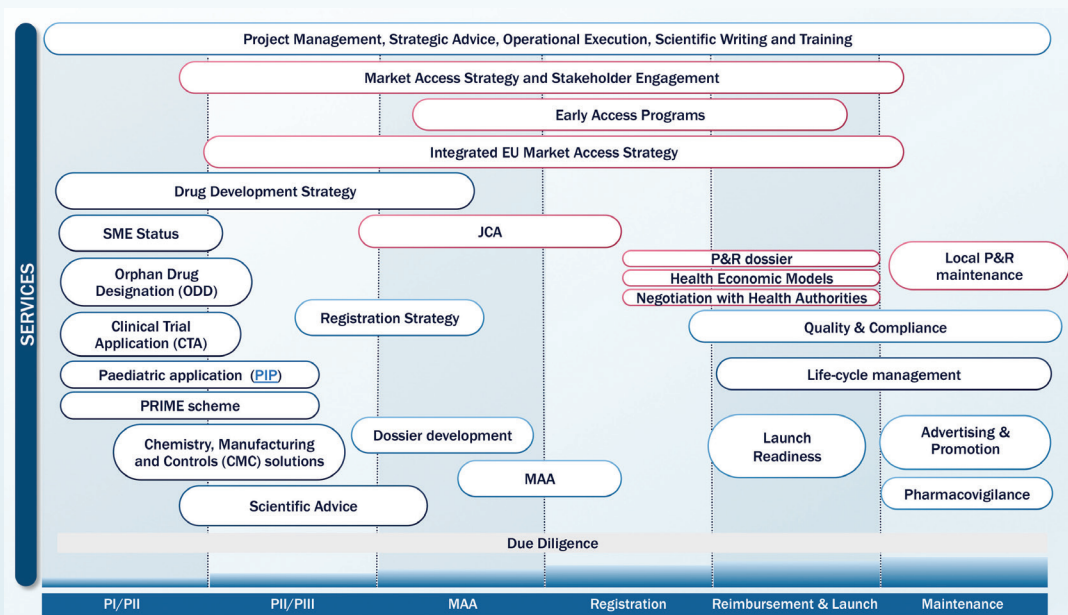
This commitment has been formally recognized through the Italian Legality Rating, issued by the Autorità Garante della Concorrenza e del Mercato (AGCM).

This rating affirms RPN's adherence to ethical conduct, transparency, and compliance with national regulations, further reinforcing our role in strengthening institutions that safeguard public health.

SERVICES OFFERED “FROM RESEARCH TO MARKET”



OUR SERVICES: INTEGRATED SOLUTIONS FOR THE FULL PRODUCT LIFECYCLE



At RPN, we provide a comprehensive suite of integrated services designed to accompany our partners through every stage of their product’s lifecycle.

Our approach connects regulatory excellence, scientific insight, and market access strategy into one seamless pathway, enabling our clients to navigate complex frameworks, accelerate innovation, and create lasting value for patients and stakeholders alike.

Our operations are built upon two strategic pillars that reflect the depth and diversity of our expertise.

Regulatory Affairs & Market Access

This pillar represents the core of our identity and the essence of our integrated approach. We deliver end-to-end solutions tailored to the distinct needs of the Life Sciences sectors we serve.

- **BioTech & Pharmaceutical**

We offer strategic and operational support that spans the full product journey, from early development to post-marketing. Our experts manage regulatory submissions, engage with health authorities, and design strategies that optimize product approval, reimbursement, and market entry, ensuring innovation reaches patients efficiently and safely.

- **MedTech**

For medical devices and technologies, we provide specialized regulatory and market access services that address the unique dynamics of the MedTech environment. Our team helps clients anticipate regulatory change, ensure compliance across jurisdictions, and achieve timely and sustainable access to key global markets.

Integrated Support Services: Empowering Innovation and Compliance

To complement our core offerings and reinforce our integrated service model, RPN provides a suite of strategic support services designed to enhance client capabilities, foster innovation, and ensure regulatory excellence across the product lifecycle.

- **RPN Academy**

We offer customized training programs for the Pharmaceutical and MedTech industries, delivered directly on-site or via the web, to maximize flexibility. Our service covers all major areas of interest within the sector and can be organized as single sessions or incorporated into complex training plans. We actively support clients in the design and execution of these plans to ensure full compliance with both internal company standards and current regulatory requirements.

- **RPN AI Lab**

Innovation is a key driver of integration. At the forefront of technological advancement, our AI Lab develops intelligent solutions that streamline regulatory workflows, analyze complex datasets, and support data-driven decision-making. These tools are embedded within our service ecosystem, enhancing agility and precision across all phases of client engagement.

- **Quality & Compliance**

Our quality and compliance services are designed to uphold the highest international standards, ensuring that systems, processes, and products consistently meet global regulatory requirements. This function operates in synergy with all service areas, safeguarding patient safety and corporate reputation while reinforcing the integrity of our integrated approach.

In-Depth Expertise for BioTech & Pharmaceutical Companies

At RPN, we provide integrated expertise that connects every stage of product development and commercialization. Our services are strategically aligned with each milestone, from early-stage planning and regulatory strategy to authorization, market access, and post-market maintenance, ensuring a seamless, compliant, and efficient journey from concept to patient. Through this holistic approach, we empower biotech and pharmaceutical companies to transform innovation into real-world healthcare solutions, accelerating access while upholding the highest standards of quality, safety, and ethics.

Early Development (PI / PII)

At RPN, the early stages of development represent the foundation upon which successful innovation is built. Through an integrated, strategic approach, we help our partners transform scientific potential into structured, regulatory-ready programs setting the course for long-term success.

Our services include:

- **Drug Development Strategy:** Designing comprehensive, forward-looking development plans.
- **Special Designations:** Guiding clients through key regulatory opportunities, including SME Status, Orphan Drug Designation (ODD), and PRIME scheme applications, to optimize incentives and accelerate development.
- **Clinical & Manufacturing Support:** Providing expert management of Clinical Trial Applications (CTA), developing tailored Paediatric Investigation Plan (PIP) strategies, and delivering robust Chemistry, Manufacturing, and Controls (CMC) solutions to ensure quality and compliance from the very start. By combining strategic insight, scientific depth, and regulatory excellence, RPN Life Solution ensures a smooth and efficient path from early innovation to clinical success.

Pivotal Trials & Regulatory Submissions (PII / PIII to MAA)

As development advances toward market approval, RPN strengthens its partnership with clients through integrated regulatory, strategic, and market access expertise. In this critical phase, our goal is to ensure a seamless transition from clinical success to regulatory authorization, laying the groundwork for sustainable market entry.

Our services include:

- **Regulatory Strategy & Engagement:** Developing a comprehensive Registration Strategy, seeking Scientific Advice from authorities, and managing Dossier Development for the Marketing Authorisation Application (MAA), ensuring clarity, consistency, and compliance at every step.
- **Market Access Preparation:** Designing an Integrated EU Market Access Strategy that connects regulatory and HTA perspectives, engaging proactively with key stakeholders, and preparing for the Joint Clinical Assessment (JCA) to facilitate smooth and timely access across Europe.

By combining regulatory insight, scientific rigor, and cross-functional coordination, RPN ensures that every submission becomes a strategic milestone transforming innovation into accessible, approved healthcare solutions.

Registration, Reimbursement & Launch

At RPN, securing marketing authorization is not the end of the journey: it's the start of delivering real value to patients and healthcare systems.

Through our integrated approach, we connect regulatory, access, and quality expertise to ensure that every innovation successfully reaches the market and maintains excellence over time.

Our services include:

- **Early Access Programs:** Providing expert guidance and support to help patients benefit from new therapies as early as possible.
- **Pricing & Reimbursement (P&R):** Developing comprehensive P&R dossiers, building strong Health Economic Models, and leading negotiations with Health Authorities to secure optimal access conditions and sustainable value recognition.
- **Launch Readiness:** Designing and executing coordinated launch plans that align regulatory, operational, and commercial activities, ensuring full preparedness for market entry.
- **Quality & Compliance:** Establishing and maintaining robust post-approval quality systems, ensuring that safety, reliability, and compliance remain uncompromised throughout the product's lifecycle.

By bridging science, strategy, and execution, RPN ensures that innovation doesn't stop at approval, it reaches patients efficiently, responsibly, and sustainably.


Maintenance & Lifecycle Management

At RPN, our commitment extends well beyond launch.

We continue to support our partners in maintaining compliance, optimizing performance, and maximizing the long-term value of their products through an integrated and proactive approach.

Our services include:

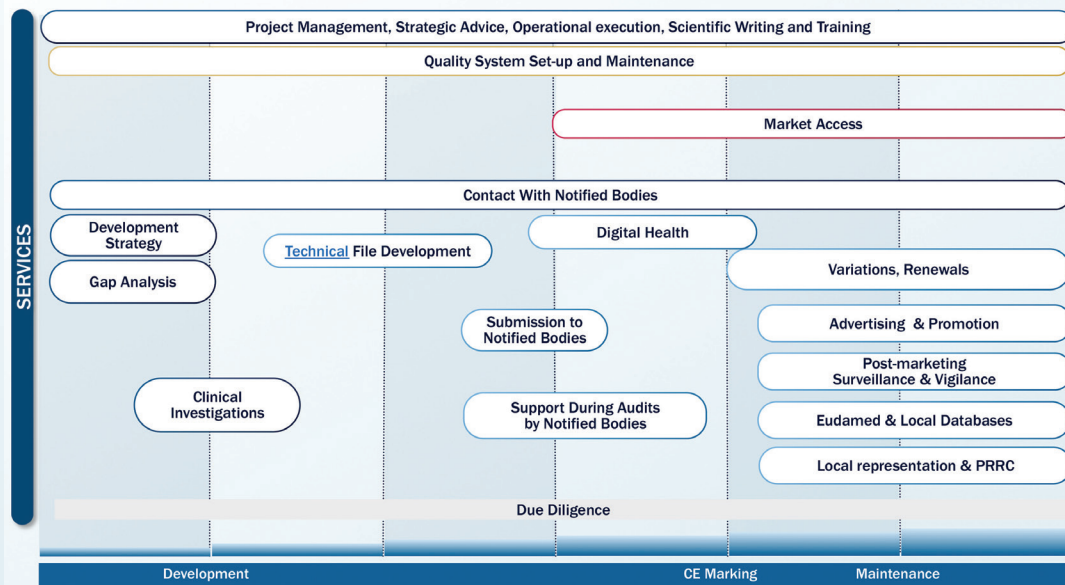
- **Post-Marketing Activities:** Managing Pharmacovigilance systems to safeguard patient safety, ensuring Advertising & Promotion compliance across markets, and overseeing Local Pricing & Reimbursement (P&R) maintenance to sustain market access.
- **Lifecycle Management:** Designing and implementing strategic adaptation plans to address new regulations, manage product variations, and extend market longevity, ensuring that every product continues to deliver value throughout its lifecycle.



Across all phases, our work is anchored by expert Project Management, Strategic Advice, Operational Execution, Scientific Writing, and Targeted Training, ensuring seamless coordination, scientific rigor, and consistent quality at every step.

Through this continuous partnership, RPN ensures that innovation remains impactful, from development to market and beyond.

EU EXPERTISE ALONG THE MEDICINAL PRODUCT LIFECYCLE



Dedicated Expertise for MedTech Innovators: Integrated Support Across the Lifecycle

Our services are specifically designed to address the unique regulatory and commercial challenges of the MedTech industry. Through an integrated approach, we ensure a seamless journey from initial development to sustained market presence, connecting strategic insight, operational execution, and compliance excellence at every stage.

Development Phase: Building a Strong, Connected Foundation

In the early stages, we focus on establishing a robust regulatory and clinical framework that aligns with future market requirements.

Our key services include:

- **Strategic Guidance:** We define a comprehensive development strategy and conduct gap analyses to proactively identify and resolve regulatory challenges, ensuring alignment across clinical, technical, and quality domains.
- **Clinical Investigations:** We provide end-to-end support for the planning and execution of clinical investigations, integrating regulatory and scientific expertise to generate high-quality data for approval.
- **Technical File Development:** Our team prepares and develops the Technical File with precision, ensuring it reflects the full spectrum of regulatory, clinical, and quality requirements, ready for submission and review.

CE Marking Phase: Coordinated Path to Market Access

This phase focuses on achieving CE Marking, a critical milestone for EU market entry. Our integrated services streamline interactions with authorities and ensure readiness across all dimensions.

Our support includes:

- **Notified Body Interaction:** We act as the central point of contact with Notified Bodies, managing submissions and providing strategic and operational support during audits.
- **Quality System & Market Access:** We assist in setting up and maintaining quality systems, while developing tailored market access strategies that align with regulatory pathways and commercial goals.
- **Specialized Support:** We offer expertise in emerging areas such as Digital Health and conduct thorough due diligence to support informed business decisions, integrating innovation with compliance.

Maintenance Phase: Sustaining Compliance and Market Success

Post-market, we ensure continued regulatory alignment and operational excellence through integrated services that support long-term product success.

Our services include:

- **Regulatory & Compliance:** We manage variations, renewals, advertising compliance, and post-marketing surveillance and vigilance, ensuring all activities remain aligned with evolving regulations.
- **Database & Representation:** We ensure compliance with Eudamed and local databases and provide Local Representation and PRRC services to maintain regulatory accountability and market presence.

Throughout every phase, our work is supported by expert project management, strategic consulting, scientific writing, training, and operational execution, ensuring a fully integrated and successful partnership tailored to the needs of MedTech innovators.

Comprehensive Due Diligence Services

To support critical investment, licensing, and acquisition decisions, RPN offers comprehensive due diligence services that are fully integrated within our broader regulatory and market expertise. This approach ensures a 360-degree evaluation of assets or companies, combining regulatory intelligence, market analysis, and operational insight to deliver a clear, actionable picture.

Our services are designed to:

- *Identify risks across regulatory, clinical, and commercial dimensions*
- *Validate opportunities through cross-functional analysis and benchmarking*
- *Provide realistic valuations based on current and future regulatory and market scenarios.*

By embedding due diligence within our integrated service model, we ensure that every assessment is informed by deep domain knowledge and aligned with the strategic goals of our clients, empowering confident, data-driven decisions in a complex and evolving Life Sciences landscape.

GOVERNANCE



ENHANCED GOVERNANCE FOR STRATEGIC GROWTH

To sharpen our strategic focus and enhance decision-making, RPN has evolved its governance model. This structure, further refined in 2024, is led by two specialized committees and a key supervisory role to ensure tight alignment between our long-term vision and daily execution.

BUSINESS COMMITTEE

This committee is the engine of our growth. It is responsible for identifying new market opportunities, aligning business development with operational capacity, and transforming innovative concepts into actionable strategies. It ensures our commercial efforts are synergistic and guided by a clear, long-term vision.

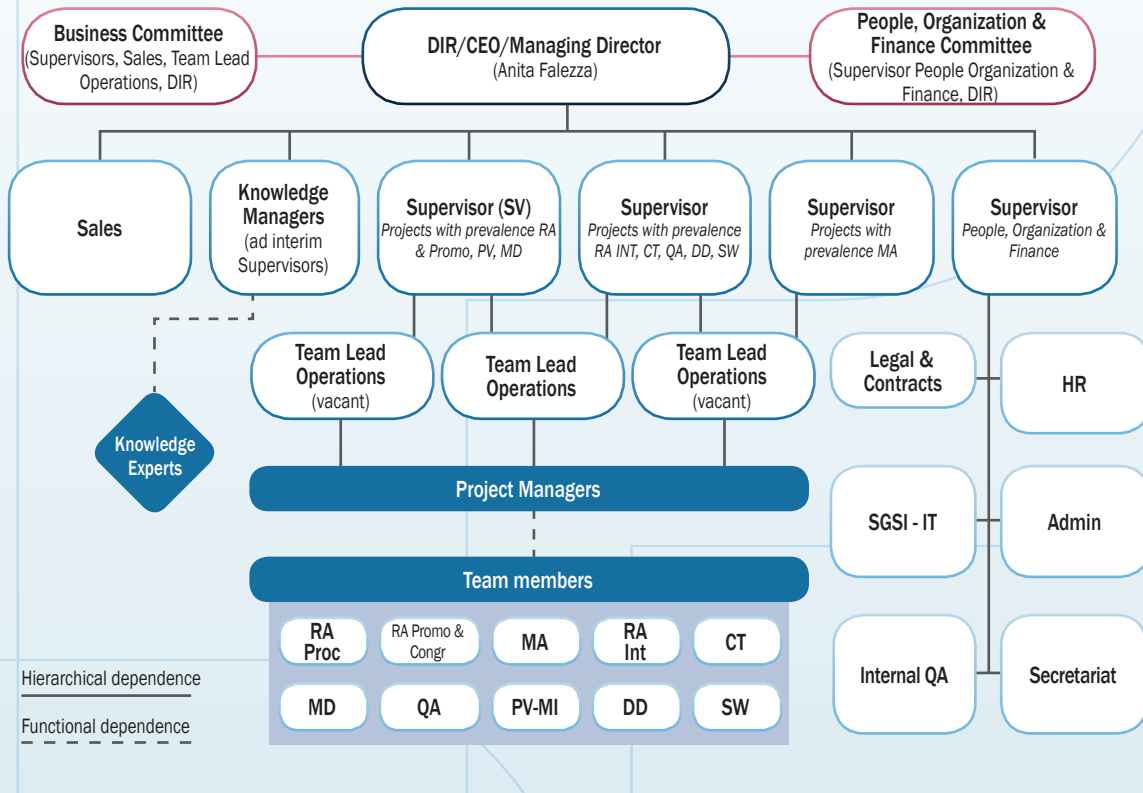
PEOPLE, ORGANIZATION, AND FINANCE COMMITTEE

This body provides the foundational strength for our success. It oversees the strategic management of our people, finances, and organizational processes. Its mission is to ensure that our teams are empowered, our resources are allocated effectively, and our operations are seamless, providing a robust platform for all company initiatives.

SUPERVISOR

This strategic role acts as the crucial link between strategy and execution. The Supervisor is responsible for driving key objectives by overseeing project management and leading business development. To enhance efficiency, the Supervisor is supported by the Team Lead Operation, who provides dedicated assistance on operational matters to ensure our strategic initiatives are implemented smoothly.

ORGANIZATIONAL STRUCTURE CHART



MANAGEMENT SYSTEM: GOVERNANCE, SECURITY, AND LEGAL INTEGRITY

RPN operates under a robust and integrated management system, designed to ensure operational excellence, regulatory compliance, and responsible business conduct across all activities.

Our commitment to quality and security is demonstrated by the following certifications, issued by Certiquality S.r.l.:

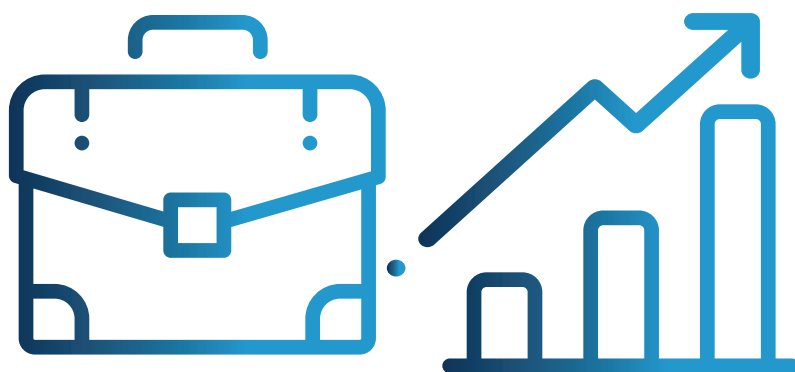
- **UNI EN ISO 9001:2015** – Quality Management
- **ISO 27001:2022** – Information Security
- **UNI/PdR 125:2022** – Gender Equality

This system is further strengthened by the presence of an in-house IT department, which ensures continuous monitoring, secure data management, and full compliance with international standards.

The internal IT infrastructure plays a strategic role in supporting operational efficiency and safeguarding information integrity across all projects and systems, reinforcing the integration between technology, quality, and compliance.

In addition, RPN has obtained the Italian Legality Rating, issued by the Autorità Garante della Concorrenza e del Mercato (AGCM). This recognition confirms our adherence to high standards of ethical conduct, transparency, and legal compliance, and further consolidates our governance framework as a pillar of stakeholder trust and corporate responsibility.

BUSINESS MODEL AND STRATEGY



OUR VALUE CREATION MODEL AT RPN

At RPN, our business model is built on strategically managing the six capitals of the International <IR> Framework. We transform these capitals into sustainable value by leveraging the unique strengths of our company.

This integrated approach ensures our growth directly benefits our clients in the Life Sciences sector, our expert team, and the wider community.

Financial Capital

The financial resources we reinvest into the business are a strategic enabler of our integrated service model. This capital supports our long-term growth, empowers the adoption of advanced technologies, including AI-driven solutions, and ensures we consistently deliver high-quality regulatory and consulting services across the entire product lifecycle. By channeling financial capital into innovation, talent development, and operational excellence, we reinforce the synergy between our core and support services, creating a cohesive ecosystem that responds dynamically to stakeholder needs and market evolution.

Human Capital

The specialized expertise and deep industry knowledge of our Life Sciences consultants and regulatory experts represent RPN's most valuable asset. Their contribution is not isolated, it is embedded within our integrated service model, where cross-functional collaboration and continuous learning drive excellence across every phase of the product lifecycle. We are committed to their ongoing professional development, ensuring they remain at the forefront of global regulatory trends and scientific innovation. Through structured training, knowledge sharing, and active participation in industry networks, our experts continuously enhance the quality, agility, and coherence of the services we deliver, transforming individual expertise into collective value.

Intellectual Capital

Our intellectual capital is built on proprietary methodologies, regulatory intelligence databases, and robust internal processes. These assets are not isolated, they are embedded within our integrated service model, enabling consistent quality, efficiency, and security across all operations. Certified under ISO 9001:2015 for quality and ISO 27001:2022 for information security, our systems ensure that every project benefits from structured knowledge, validated practices, and secure data handling, supporting informed decisions and regulatory precision.

Social & Relationship Capital

We cultivate long-term, trust-based relationships with pharmaceutical and MedTech clients, regulatory authorities, and industry partners. These external connections are mirrored internally by a collaborative culture that enhances cross-functional integration and knowledge sharing. Our commitment to gender equality, certified by UNI/PdR 125:2022, reinforces inclusive practices and strengthens our social fabric, making relationship capital a key driver of cohesion, innovation, and stakeholder engagement. In 2024, we also adopted a new Customer Relationship Management (CRM) system to strengthen our client engagement strategy. This digital tool enables us to manage interactions more effectively, personalize service delivery, and gain deeper insights into client needs and expectations. The CRM is now fully integrated into our operations, supporting our commitment to responsiveness and long-term relationship, building key pillars of our Social & Relationship Capital.



Manufactured Capital

Our manufactured capital includes a secure IT infrastructure, specialized software, and modern office environments that support seamless collaboration and data protection. These assets are strategically aligned with our integrated service delivery, enabling teams to manage sensitive client information securely and efficiently, whether working on-site or remotely. By investing in resilient, scalable systems, we ensure that our operational backbone supports agility, compliance, and excellence across the entire product lifecycle.

Natural Capital

As a service-based company, RPN is committed to minimizing the environmental impact of its operations through an integrated approach to sustainability. We focus on responsible energy consumption, waste reduction, and sustainable procurement, embedding these principles into our daily practices and decision-making processes. We are preparing to further validate our efforts by pursuing the EcoVadis sustainability rating in the coming year. By aligning environmental responsibility with our integrated service model, we ensure that sustainability is not a separate initiative, but a core component of how we operate, deliver value, and contribute to a healthier future.

RISK MANAGEMENT



COMMITMENT TO QUALITY, SECURITY AND RESPONSIBILITY

RPN's commitment to excellence and responsible business practices is demonstrated by its robust management system certifications, including ISO 9001:2015 for quality, ISO 27001:2022 for information security, and UNI/PdR 125:2022 for gender equality, all certified by Certiquality S.r.l. To ensure full compliance with these standards, our in-house IT department plays a pivotal role in safeguarding data integrity, maintaining secure infrastructures, and ensuring business continuity across all operations.

This technical governance reinforces our integrated approach to quality, security, and inclusion key pillars of our sustainable growth.

DOCUMENTATION AND GOVERNANCE

Our management framework is built on structured and dynamic documentation: a comprehensive Quality Manual and detailed operational procedures, continuously updated by process owners and the QA team, with strategic support from our internal IT department.

Each revision is part of a fluid digital ecosystem, where information remains accessible, consistent, and aligned with evolving processes.

This ensures that every service, fully integrated within the brand's new positioning, is driven by quality, transparency, and innovation.

CORRECTIVE AND PREVENTIVE ACTIONS (CAPA)

Our CAPA process is now driven by mature, automated workflows, developed through close collaboration between the QA team and our internal IT department.

These integrated digital systems not only ensure a structured and timely response to non-conformities but also connect seamlessly with other business processes, enhancing service consistency and operational synergy.

The 2024 review confirmed the effectiveness of these solutions in resolving issues efficiently and preventing recurrence, reinforcing our commitment to an agile, integrated, and excellence-driven service model.

STAFF TRAINING AND SUPPLIER MANAGEMENT

Staff training on quality documentation is managed through an automated system that monitors completion rates in real time and keeps the Training Register up to date, ensuring traceability, efficiency, and consistency. In 2024, we also took a strategic step forward with the full implementation of a new IT tool for supplier management.

This platform, now fully operational, is a core component of our digital ecosystem and enables structured and transparent supplier qualification, re-evaluation, and categorization.

A system that not only enhances decision-making quality but also strengthens supply chain integrity and supports the evolution toward an integrated, agile, and quality-driven service model.

INFORMATION SECURITY

Our Information Security Management System (ISMS) is fully aligned with the ISO 27001:2022 standard and represents a cornerstone of our operational governance. In 2024, we strengthened this system with the establishment of a dedicated in-house IT department, which now serves as a central pillar of our security and business continuity strategy.

This internal structure plays a decisive role in safeguarding our digital ecosystem, ensuring the protection, integrity, and availability of information across all projects and platforms.

Through continuous monitoring, advanced data management, and direct oversight of critical infrastructures, our IT team ensures that cybersecurity and operational excellence remain deeply embedded in every aspect of our organization. We maintain a proactive security posture through regular vulnerability assessments and penetration tests on all critical systems, guaranteeing the highest level of data protection for both our clients and our company.

DIGITAL INNOVATION AND PROCESS OPTIMIZATION

Our digital innovation program continued to advance throughout 2024. We are actively integrating artificial intelligence (AI) and other advanced tools to optimize our data management processes and enhance internal knowledge sharing.

This ongoing initiative positions RPN at the forefront of technological adoption in our sector, driving efficiency and innovation. Digital transformation is a fundamental component of RPN's integrated services model.

Throughout 2024, our digital innovation program continued to evolve, reinforcing the connection between technology, regulatory expertise, and strategic operations. We are progressively embedding artificial intelligence (AI) and other advanced digital tools within our core services, from data management and regulatory analysis to project coordination and knowledge sharing. This approach enhances precision, efficiency, and collaboration across all business areas, creating seamless connections between teams and disciplines.

Looking ahead, in 2025 we plan to launch training programs dedicated to the responsible and effective use of digital technologies and AI, ensuring that every professional within RPN can fully harness these tools to deliver smarter, faster, and more value-driven solutions for our partners.

Through this continuous alignment between technology and expertise, RPN strengthens its position as a forward-looking partner capable of combining innovation, compliance, and strategic insight across the entire life sciences value chain.

STAKEHOLDER ENGAGEMENT



STRATEGIC LEVER FOR INTEGRATED AND DIGITAL VALUE CREATION

In 2024, meaningful stakeholder engagement remained a cornerstone of RPN's strategy, fully aligned with our renewed brand identity and integrated service model. Today, thanks to the evolution of our digital ecosystem and the adoption of AI-powered solutions, stakeholder dialogue has become more insightful, timely, and strategic.

Digital technologies enable us to collect, analyze, and interpret feedback in real time, generating high-value insights that inform decision-making and strengthen the connection between strategic vision and operational execution.

Guided by the principle of materiality, this report focuses on the topics that most significantly impact our ability to generate sustainable value. In 2024, we refreshed our materiality analysis through a structured process involving both internal management and external stakeholders.

The integration of digital tools and artificial intelligence into this process allows us to identify and prioritize the issues most relevant to our business and to those we serve, accelerating our evolution toward an agile, interconnected, and quality-driven service model.

RPN is strengthening its international presence through a strategic, digitally empowered approach:

Strategic Partnerships

We cultivate alliances with key stakeholders across EU and non-EU markets, leveraging digital tools and AI-driven insights to navigate complex regulatory frameworks and unlock new commercial opportunities. These partnerships are not only commercial but also strategic, enabling scalable integration of services across diverse geographies.

Global Network & Knowledge Exchange

Our active participation in leading organizations such as Eucope and Ispor enhances our global visibility and ensures continuous alignment with industry best practices. Through digital platforms and AI-enhanced collaboration tools, we maintain a dynamic exchange of knowledge, fueling innovation, compliance, and strategic foresight. This dual strategy reinforces our commitment to delivering smart, integrated, and future-ready services across the life sciences value chain.

Project Management

At RPN, project management is not just operational, it's strategic. Our evolved framework places the Supervisor role at the heart of delivery, ensuring that every project aligns with corporate objectives, client expectations, and resource optimization.

This structure is powered by advanced, data-centric tools that enable real-time monitoring of hours, resources, and performance indicators. Monthly reporting processes are fully digitalized, providing transparent insights that support agile decision-making and reinforce client trust.

Our commitment to continuous improvement is reflected in the ongoing review of roles, tools, and workflows. By embedding automation and AI into our project governance, we foster a culture of adaptability, precision, and excellence, ensuring that every service we deliver is smart, integrated, and future-ready.

Empowering People

At RPN, our people are our most valuable asset and we invest in their growth through a digitally integrated and inclusive framework.

In 2024, we proudly achieved the UNI/PdR 125:2022 certification, affirming our commitment to gender equality and a workplace culture rooted in equity, transparency, and respect.

This milestone reflects our strategic focus on inclusion as a driver of innovation and sustainable value.

Our structured development program organizes talent into five professional clusters, enabling personalized career paths and targeted skill-building. This model is supported by a merit-based performance evaluation system and an enhanced corporate welfare plan, ensuring that every team member feels recognized, supported, and empowered. Digital tools play a central role in managing training, performance, and career progression, creating a seamless, data-driven ecosystem that fosters continuous learning and strategic alignment. Through this integrated approach, we cultivate a resilient, future-ready workforce capable of delivering excellence across the life sciences value chain.

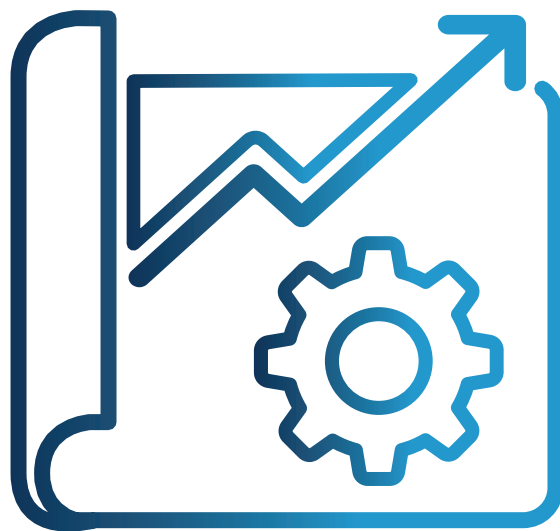
AI and Digitalisation

In the data-intensive world of Life Sciences, embracing digital transformation and Artificial Intelligence (AI) is not just a choice, it's a strategic imperative. At RPN, we see these technologies as key enablers of efficiency, precision, and strategic insight.

We are actively integrating advanced digital tools to streamline internal processes and enhance service delivery.

This digital-first approach is embedded across our operations, delivering superior value through robust data analytics, seamless collaboration, and smart automation. All of this is built on the secure foundation of our ISO 27001:2022 certified infrastructure, ensuring data integrity, availability, and protection.

OUR STRATEGIC BLUEPRINT



STRATEGIC EXECUTION FOR SUSTAINABLE, DIGITAL-DRIVEN GROWTH

In 2024, RPN successfully executed its strategic roadmap, building on the transformative momentum of the previous year and delivering measurable value to stakeholders. Our approach was anchored in three core pillars, each enhanced by digitalization and AI:

Customer-Centricity

We placed our clients at the center of every decision, delivering tailored, data-informed solutions that strengthened trust and long-term partnerships. AI-powered insights and digital platforms enabled us to anticipate needs and personalize service delivery at scale.

Internationalization

We expanded our global footprint, deepening engagement in key markets and leveraging our international network to deliver consistent, high-quality results. Digital tools facilitated seamless collaboration across borders.

Service Quality

Operational excellence remained a top priority. Through smart automation, real-time analytics, and continuous process optimization, we ensured our services not only met but consistently exceeded expectations.

This strategy is fully integrated within our business model, aligned with the six capitals of the IIRC framework: Financial, Manufactured, Intellectual, Human, Social & Relationship, and Natural. By embedding digital transformation and AI across these dimensions, we create sustainable, long-term value and reinforce our role as a future-ready partner in the life sciences ecosystem.

SHAPING THE FUTURE THROUGH INTEGRATION, INNOVATION AND IMPACT

Following a transformative 2024, marked by our full brand refresh and the achievement of the UNI/PdR 125:2022 Gender Equality certification, RPN enters 2025 with a clear mission: to deepen our capabilities, accelerate innovation, and reinforce our commitment to responsible business practices. Our strategic priorities reflect a cohesive vision, aligned with the six capitals of the IIRC framework and our journey toward obtaining the EcoVadis sustainability rating, a milestone that will validate our integrated approach to quality and environmental responsibility.

Deepening Global Partnerships

We aim to maximize the impact of our international collaborations and memberships, leveraging digital platforms and shared intelligence to deliver consistent, high-quality results across borders.

Embedding Our Culture of Inclusion

Building on our gender equality certification, we continue to foster a diverse and equitable workplace that attracts, retains, and empowers top talent, making inclusion a driver of innovation and resilience.



Amplifying Our New Brand

Through targeted digital campaigns, a refreshed online presence, and strategic storytelling, we are increasing market visibility and positioning RPN as a trusted, future-ready partner in the life sciences ecosystem.

Investing in Expert Growth

Our training programs are evolving to focus on advanced competencies in AI, data analytics, and global strategic consulting, ensuring our team remains at the forefront of industry transformation.

PERFORMANCE 2024



FINANCIAL CAPITAL

In 2024, RPN maintained a robust financial position, ensuring the stability and resources needed to drive growth and deliver exceptional value to our stakeholders.

2024 Highlights

- **Equity: 100%**
- **Net Financial Position: 11.000.000 €**
- **Turnover: 6.300.000€**
- **Value distributed to stakeholders: more than 5.000.000 €**

Our strong performance enabled us to distribute significant value to our stakeholders, including employees, suppliers, and the community. Our accounting structure, enhanced with advanced digital tools, continues to provide a solid foundation for financial management and operational efficiency.

ORGANIZATIONAL CAPITAL

We continued to strengthen our organizational assets in 2024, with a strategic focus on security, quality, and the integration of artificial intelligence.

Information Security (ISMS)

Our ISO 27001:2022 certified ISMS remains a cornerstone of our operations. Throughout 2024, we continuously improved our cybersecurity posture with advanced tools and comprehensive staff training to protect client and company data.

Quality Management (QMS)

We reaffirmed our commitment to the highest service standards by maintaining our ISO 9001:2015 certification, ensuring excellence in every project we deliver.

Digitalization and AI

Digitalization is now fully embedded in our operations, streamlining workflows and enhancing collaboration. Building on our 2023 strategic plan, in 2024 we began actively integrating AI tools into our processes. This initiative is advancing our evolution towards a more innovative, data-driven management approach, positioning us at the forefront of the industry.

INFRASTRUCTURAL CAPITAL

Our headquarters in Pisa reflects RPN's commitment to creating a work environment that fosters well-being, collaboration, and operational excellence.

Premium amenities, such as a fully equipped kitchen, contribute to a welcoming and efficient atmosphere, while sustainability initiatives, like promoting the use of reusable water bottles, reinforce our values of responsibility and environmental awareness, in line with our journey toward the EcoVadis sustainability rating.

This physical space is not just a location, it's a strategic asset that supports our integrated service model, enhances team synergy, and reflects our culture of innovation, inclusion, and continuous improvement.

Human Capital

At RPN, our people are the driving force behind our success. In 2024, we strengthened our commitment to growth, well-being, and empowerment, aligning our human capital strategy with our integrated, digital-first business model.

Gender Equality Achievement: We proudly achieved the UNI/PdR 125:2022 certification, confirming our dedication to building an inclusive and equitable workplace where every individual can thrive.

Career Growth Framework: Our structured development program, based on five professional clusters (from Specialist to Director), provides clear, personalized career paths that support long-term growth and strategic alignment.

Continuous Learning: We maintained a strong focus on training, combining technical and soft skills in a structured plan that prepares our professionals to meet evolving market demands with agility and confidence.

Well-being and Flexibility: Our expanded corporate welfare plan and smart working model remain central to our strategy, promoting a healthy work-life balance and sustaining high levels of motivation.

Talent and Engagement: In 2024, our HR team evolved with the addition of a Talent Acquisition & Development Specialist, enhancing our ability to attract top expertise and support continuous improvement.

We also introduced Open Talks with HR, creating dedicated spaces for dialogue, feedback, and shared growth. These sessions complement our annual performance evaluation process, which is designed to be fair, transparent, and aligned with individual and organizational goals.

Team Building: Our team building activities played a key role in strengthening collaboration, trust, and a sense of belonging, fostering a dynamic and cohesive work environment.

This people-centric strategy is fully integrated into our broader vision of delivering smart, inclusive, and sustainable services, where technology and talent work together to shape the future of life sciences.

SOCIAL CAPITAL

A New Brand for a New Era

One of the key milestones of 2024 was the launch of our new corporate identity, marking a strategic evolution in how we present ourselves to the world. The rebranding initiative included a redesigned logo and a completely revamped website, aligning our external image with our internal transformation. Our new brand reflects RPN's commitment to innovation, digitalization, and global impact. It positions us as a forward-thinking partner in the Life Sciences industry: agile, integrated, and ready to meet the challenges of a rapidly evolving market.

The new website serves as our central digital hub, offering a more intuitive, engaging, and accessible user experience. It provides deeper insights into our services, expertise, and company culture, strengthening our connection with clients, partners, and stakeholders.

Strategic Communication and Digital Visibility

RPN enhanced its online presence, particularly on LinkedIn and the corporate blog, by sharing high-value content on key topics such as Regulatory Affairs, Medical Devices, Market Access, Pharmacovigilance, and Drug Development.

This digital storytelling not only fostered active dialogue with current and potential stakeholders but also served as a strategic lever to communicate the value of RPN's integrated service model.

By aligning content with stakeholder interests and showcasing cross-functional capabilities, RPN strengthened brand awareness and reinforced its reputation as a reliable, forward-thinking partner in the Life Sciences sector.

This approach reflects the principles of GRI 102-43 and 102-44, demonstrating how targeted communication can support stakeholder engagement and highlight the coherence of integrated services.

Anonymous Survey and Feedback Culture

To deepen its understanding of stakeholder expectations, RPN conducted an anonymous Business Unit survey focused on customer satisfaction. While the survey captured feedback at a unit level, its strategic value extended far beyond: the digital-first approach enabled efficient data collection and cross-functional analysis, transforming individual insights into shared knowledge.

These insights became a catalyst for internal dialogue, nurturing a robust feedback culture and guiding targeted enhancements to service delivery.

By circulating results across teams, the initiative reinforced the integration between operational areas, aligning services more closely with stakeholder needs and expectations.

The survey results revealed a strong level of trust and appreciation, with stakeholders consistently recognizing RPN's quality, professionalism, customer-centric mindset, and reliability.

This initiative exemplifies the principles of GRI 102-43 and 102-44, demonstrating how structured stakeholder engagement, when combined with digital tools and internal collaboration, can directly support integrated service models and long-term value creation.

Internal Engagement

RPN actively encourages employee participation in generating and sharing strategic insights.

This continuous flow of knowledge not only enriches the company's vision but also plays a key role in strengthening the integrated service model, ensuring that expertise from different domains converges to address stakeholder needs in a coordinated and agile manner.

By fostering a collaborative and improvement-oriented internal culture, RPN enhances its ability to anticipate and respond to emerging expectations, translating individual contributions into collective value.

This approach reflects the principles of GRI 102-43 and 102-44, demonstrating how internal engagement and knowledge sharing directly support stakeholder responsiveness and service integration.

Strategic Partnerships and Networks

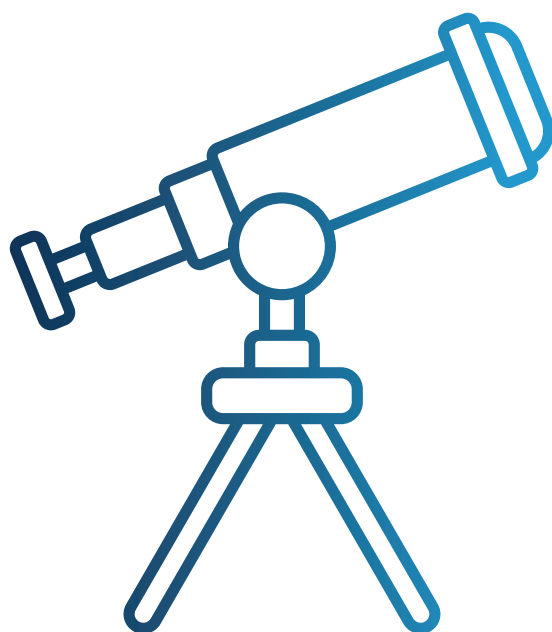
In 2024, RPN intensified its involvement in key industry associations such as EUCOPE and ISPOR, while strengthening collaborations with regulatory and market access partners across Europe and the United States.

These strategic alliances not only expanded RPN's international footprint but also reinforced the company's integrated service model, enabling the seamless connection of local expertise with global perspectives to deliver comprehensive, high-impact solutions. Looking ahead, RPN will further consolidate its global engagement by participating in the RAPS (Regulatory Affairs Professionals Society) conference in 2025.

This international event represents a valuable opportunity to engage with the global regulatory community, exchange insights, and stay aligned with emerging trends that directly inform and enhance the company's integrated service offering.

This approach reflects the principles of GRI 102-43 and 102-44, demonstrating how stakeholder engagement at a global level, through strategic networking and knowledge exchange, can strengthen service integration and contribute to long-term value creation.

OUTLOOK



OUR PERFORMANCE IN 2024: DELIVERING VALUE THROUGH TRANSFORMATION

2024 marked a pivotal year for RPN, where strategic execution and organizational evolution translated into strong performance and measurable impact.

Our streamlined structure enabled agile decision-making and greater flexibility, allowing us to deliver tailored, high-value solutions to our clients.

Guided by a data-driven mindset, we fostered a virtuous cycle of continuous improvement, where performance monitoring directly informed strategic refinement.

This approach supported sustained turnover growth, the acquisition of new global projects, and the consolidation of trust-based relationships with existing clients.

A key focus was the amplification of our refreshed brand identity.

Through the strategic rollout of our new logo and redesigned website across all digital channels, we significantly enhanced our visibility, credibility, and stakeholder engagement.

STRATEGIC PRIORITIES FOR 2025: ACCELERATING SMART, INCLUSIVE GROWTH

Building on the momentum of 2024, our strategy for 2025 is centered on leveraging our renewed identity and enhanced capabilities to drive the next phase of innovation and global impact.

Driving AI-Powered Solutions

We will actively develop and deploy AI tools to enhance service delivery, optimize internal workflows, and provide clients with predictive regulatory insights.

Deepening Global Partnerships

Our focus will shift from expanding our network to maximizing strategic value through deeper engagement with international partners and industry memberships.

Embedding Our Culture of Inclusion

Building on our Gender Equality certification, we will continue to foster a diverse and equitable environment that attracts, retains, and empowers top talent.

Investing in Expert Growth

Our training programs will evolve to focus on advanced skills in AI, data analytics, and strategic global consulting, ensuring our team remains at the forefront of industry transformation.

This strategy reflects our commitment to delivering smart, integrated, and future-ready services, aligned with our brand promise and the evolving needs of the life sciences ecosystem.



Regulatory Pharma Net Srl

Corso Italia, 116 - 56125 Pisa Italy

Phone: +39 050 9134

www.rpngroup.com