

INTEGRATED REPORT

2022



Regulatory
Pharma
Net

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LETTER TO STAKEHOLDERS



GRI 102-1, 14

I am happy to share the Integrated Report for Regulatory Pharma Net (RPN) for the year 2022. This report is designed to offer a comprehensive view of our value creation journey throughout the year to all our stakeholders.

At RPN, our value generation has been twofold:

- We have fostered quality and innovation within our service offerings, staying alert to market shifts and regulatory changes.
- We have also focused on our team, encouraging their professional development and active engagement in the company's growth.

Our commitment extends beyond just financial gains; we place a strong emphasis on nurturing a supportive work environment that respects the work-life balance of our staff, and we dedicate ourselves to generating and sustaining robust partnerships with our clients and collaborators.

We present this report voluntarily, aspiring to set a precedent for corporate transparency, a trait we believe not only fosters trust but also serves as a strategic differentiator in our industry.

Managing Director
Anita Falezza

LETTER TO STAKEHOLDERS

ABOUT THIS REPORT METHODOLOGICAL NOTE

ABOUT THIS REPORT METHODOLOGICAL NOTE



GRI 102-45, 46, 49, 50, 52

Regulatory Pharma Net Srl (RPN) voluntarily publishes its Integrated Report which aims to benefit all stakeholders interested in the organization's ability to create value over time, including employees, customers, suppliers and business partners.

This Report, in line with the evolutions of reporting at international level, is prepared in compliance with the International <IR> Framework issued in December 2013 and revised in January 2021 by the International Integrated Reporting Council (IIRC) and it uses a set of indicators selected among those proposed by the GRI Standards 2016. It is also a compliance effort made in direction of the recent regulatory evolutions regarding non-financial disclosure (Italian Legislative Decree 254/2016). Moreover, this generates an additional benefit to RPN in case of recourse to the capital market as a possible future evolution.

What is the main goal of this Integrated Report?

TRPN Integrated report has been structured to provide stakeholders with financial and non-financial information relevant to them. The "material focus areas" were determined considering the following:

- Matters critical in relation to achieving strategic objectives
- Key risks identified through a risk management process
- Feedback from key stakeholders during the year

The reporting scope includes Regulatory Pharma Net Srl and refers to the 2022 fiscal year (January 1st - December 31st).

What is indicated in the Integrated Report?

The main sources of data and information regard:

- Company management and accounting systems
- Stakeholder Engagement Project
- Risk Assessment

The contents of the Integrated Report have been approved on September 1st, 2023 by the Board of Directors. It is available on the Company's website at www.regulatorypharmanet.com.

HIGHLIGHTS



GRI 102-7

EQUITY

100%

NET FINANCIAL POSITION

more than
2,500,000€



TURNOVER

more than
5,800,000€



VALUE DISTRIBUTED
TO STAKEHOLDERS

more than
5,000,000€



CLIENTS

more than
140



LOYALTY RATE

80%

QUALITY MANAGEMENT
SYSTEM CERTIFICATION

ISO 9001:2015 & ISO 27001:2017



AVERAGE TRAINING HOURS
PER EMPLOYEE

more than
100



CUSTOMER SATISFACTION

3,56/4



QUALIFIED SUPPLIERS

100%





A. ORGANISATIONAL OVERVIEW

CORPORATE IDENTITY

Regulatory Pharma Net (RPN), founded in Italy in 1999, represents one of the leading players in the Life Science service provider market with a strong vocation for international growth.

RPN is a UNI EN ISO 9001:2015 certified service company, with a strong commitment to deliver a high-quality level of services to its customers. RPN offers consulting and services throughout the entire lifecycle product (mainly medicinal products and medical devices) from development to registration, market access, launch and maintenance, positioning itself as a one-stop shop where several specialized skills work together, generating efficient and coherent solutions.

RPN has an international vocation, with the ability to understand the needs of both national and international customers and to adapt its offering to the specific needs of each specific customer.

RPN manages both international projects (e.g. involving EMA, US FDA and other Competent Authorities worldwide) or national specific activities (e.g. lifecycle management, local RA and MA activities).

CORE VALUES

GRI 102-16

The core values built up over the years that guide Regulatory Pharma Net's internal conduct as well as its relationships with customers, partners and suppliers, are:

- Excellence
- Customer centricity
- Expertise from experience
- Agility

SUSTAINABLE DEVELOPMENT

SUSTAINABLE DEVELOPMENT GOALS 2030: SOMETHING IS CHANGING

- In **1987**, the concept of sustainability was born. According to it "the development shall meet the needs of the present generation without compromising those of the future generations"
- In **2015**, the United Nations launches a challenge to institutions, businesses and citizens with the 17 Goals for the Sustainable Development (also known as SDGs) to which contribute within 2030
- **Today** companies are not sustainable enough yet. The economic and financial goals still prevail over the social and environmental consequences and impacts.

Throughout 2022, RPN has chosen to pursue the same 7 Goals achieved in 2021 through its daily commitment:



Good health and well-being



Quality Education



Gender equality



Decent work and economic growth



Industry, Innovation and Infrastructure



Responsible consumption and production



Climate Action

SERVICES OFFERED

“FROM RESEARCH TO MARKET”



GRI 102-2

- Regulatory Pharma Net services span the entire lifecycle of a lifescience product, from development to post marketing and cover all regulated areas:
 - Development
 - Global and Local Regulatory Affairs
 - Pharmacovigilance
 - Market Access
- Thanks to its expertise and experience RPN can provide both strategic advice and support in the operational execution. RPN offers specialized and differentiated expertise in a one-stop shop, generating a strategic vision which spans across the multiple aspects to be considered during the entire lifecycle of a medicinal or healthcare product. The areas in which RPN offers consulting and services are multiple, complex and interconnected. Thanks to the unique combination of its vertical and cross-cutting competencies, it offers both strategic and operational services that integrates them, and thus moves clients fluidly and effectively. As a client-driven company, RPN services are flexible enough to be used for a complete outsourcing package or as just stand-alone services.

DEVELOPMENT AND PROJECT MANAGEMENT

RPN has wide experience across all key elements required to build a robust product development strategy. Getting a new lifesceience product is a complex process that requires specific know-how in different areas. RPN offers a team to assist the client to plan Quality (CMC), Safety (Nonclinical), and Efficacy (Clinical) studies. RPN has wide experience in managing successful submissions and meetings with the Regulatory Authorities during development, including Scientific Advices.

PRE-SUBMISSION ACTIVITIES AND MARKETING AUTHORISATION APPLICATIONS

RPN provides strategic and operational support for pre-submission activities in EU and US, such as Orphan Drug Applications to EMA and FDA, Paediatric Investigation Plan (PIP) applications, Pre-submission meetings and Management of administrative pre-submission activities.

RPN supports companies in the preparation and revision of dossiers (CTD modules 1 to 5) for Marketing Authorisation Applications. Its activities include the management of the regulatory procedures in coordination with the Client's teams and contacts with Regulatory Authorities together with the Client or on behalf of the Client.

RPN SERVICES

- Development Plan
- Third party Vendor Selection & Management
- Scientific Advice PIP

- Management of Registration Procedures
- Response Documents

- Early Access Programs
- P&R Strategy
- P&R Dossier Preparation & Negotiation

- Overall Regulatory Maintenance Variations, Renewals
- Promotional Material & Congresses

DEVELOPMENT

MARKETING AUTHORISATION

MARKET ACCESS

MAINTENANCE

- Orphan Drug Application
- Clinical Trial Applications
- IMPDs INDs

- CTD Modules
- E-CTD

- Company Budget Pay Back
- Pre-Launch

- Pharmacovigilance
- Medical Information

MARKET ACCESS

Early Access

Early access is a mechanism that enables patients with an unmet medical need to be provided with access to a medicine, prior to it being made commercially available in that country.

RPN combines its deep insight of local rules and sound experience to support the involved stakeholders in the assessment of a possible early access strategy and in the relevant implementation.

Pricing & Reimbursement (P&R)

Successful launch is the second major value point in a drug's life cycle, is it contingent upon additionally demonstrating cost-effectiveness to payers.

RPN has the capability to provide assistance in the definition of the P&R strategy, in preparation and submission of the P&R dossier compliant with the local requirements and in negotiation with the authorities to achieve a good deal. RPN has a consolidated experience with medicinal products falling within different therapeutic areas, most of them being orphan and very innovative drugs. A specific expertise is provided also with regards to Pharmacoeconomics aspects.

Pre-Launch

Besides P&R, several local regulatory requirements need to be fulfilled in order to place a medicinal product on the market. RPN fully supports its clients to reach a successful and timely launch.

REGULATORY AFFAIRS MAINTENANCE

RPN supports companies in managing the entire product life cycle for nationally, MRP, DCP and centralised registrations. For maintenance activities RPN plays the role as Regulatory Affairs Department in order to carry out all activities needed to maintain the marketing authorisations.

PHARMACOVIGILANCE

RPN has a wide expertise in pharmacovigilance activities and is the contact for pharmacovigilance for many clients from Europe, USA, Asia and Australia. It supports its clients with any local pharmacovigilance activities, acting as the point of contact with the authorities and providing advice on regulatory requirements. RPN service portfolio also includes support for the implementation of the appropriate pharmacovigilance system and to the preparation of the proper pharmacovigilance agreements in line with the requirements, GVP auditing, literature monitoring, and advice on regulatory requirements.

MEDICAL DEVICES

RPN has a wide expertise supporting companies that produce, market and import medical devices and in vitro diagnostic devices, which are interested in marketing their devices into the Italian territory or the European Union. RPN performs audits for companies and suppliers, identifies qualified laboratories to conduct tests on devices, supports the market access of medical devices and in vitro diagnostic devices including revision and submission of advertising material. RPN also collaborates with international experts able to provide support to companies interested in non-European markets.

QUALITY MANAGEMENT AND GXP AUDITING

RPN supports its clients in implementing their quality systems for the fulfilments of regulatory requirements for many product categories, from medicinal products to medical devices or in vitro diagnostic devices. Clients are guided through the implementation of the appropriate quality system (including the pharmacovigilance system, GMP quality system, quality system for manufacturers of medical devices, etc.), the revision of the technical documentation and the audits at companies and suppliers.

QUALITY ASSURANCE AND GMP AUDITING

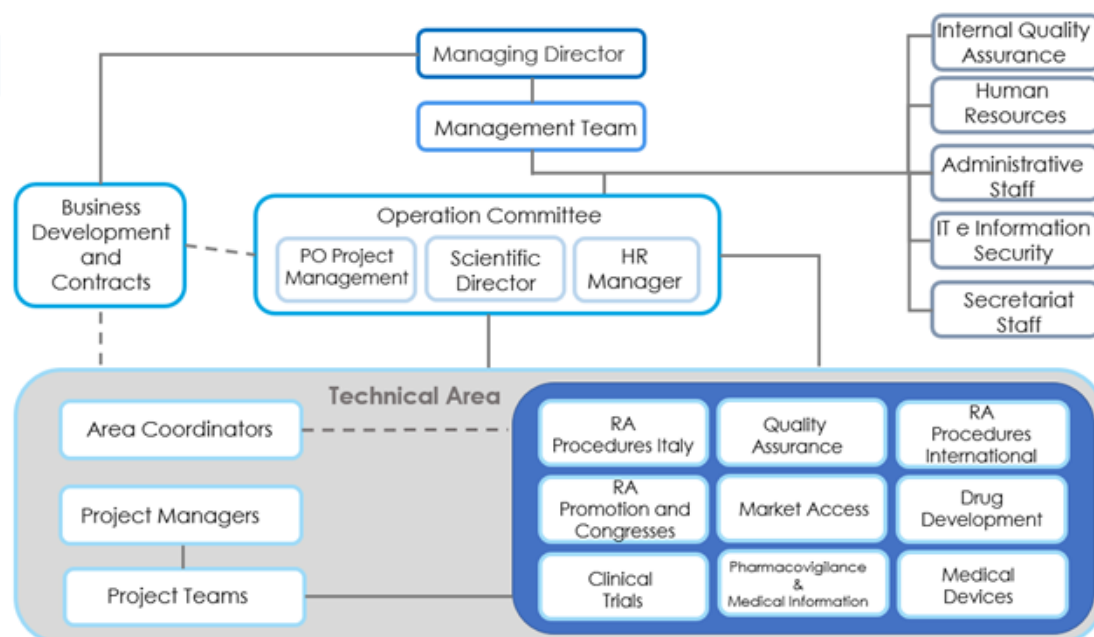
RPN team has a wide experience and a deep knowledge of GMP issues, with a record of successful projects supporting manufacturing companies.

RPN has the expertise to support its clients in the obtainment and maintenance of GMP certificates and manufacturing authorisations through quality and GMP gap analysis; GMP auditing; CAPA plan and support for contacts with the authorities.



B. GOVERNANCE

ORGANISATIONAL STRUCTURE CHART



MANAGEMENT SYSTEM

RPN has a ISO 9001:2015 and ISO27001:2017 Management System certified by Certiquality S.r.l.





C. BUSINESS MODEL AND STRATEGY

RPN BUSINESS MODEL

RPN BUSINESS MODEL

RPN business model reported below shows its system of value creation by transforming inputs, through its business activities, into outputs and outcomes aiming at fulfilling the organisation's strategic purposes and create value over the short, medium and long term.

According to IIRC the value created by RPN, transforming inputs into outputs and outcomes, is shared among 6 different capitals:



Financial capital – The Financial capital available represents the fundamental input for the realization of all the investments necessary for the correct provision of the service and customer satisfaction.



Infrastructural capital – Headquarter offices as well as all the equipment necessary for carrying out the operations.



Organisational capital – The internal processes and procedures useful for the management of the organization largely based on knowledge and the activities aimed at guaranteeing the quality of the services offered with a view to continuous improvement.



Human capital – The skills, know-how, the commitment and motivation of an organization's personnel which affect their ability to fulfil their roles.

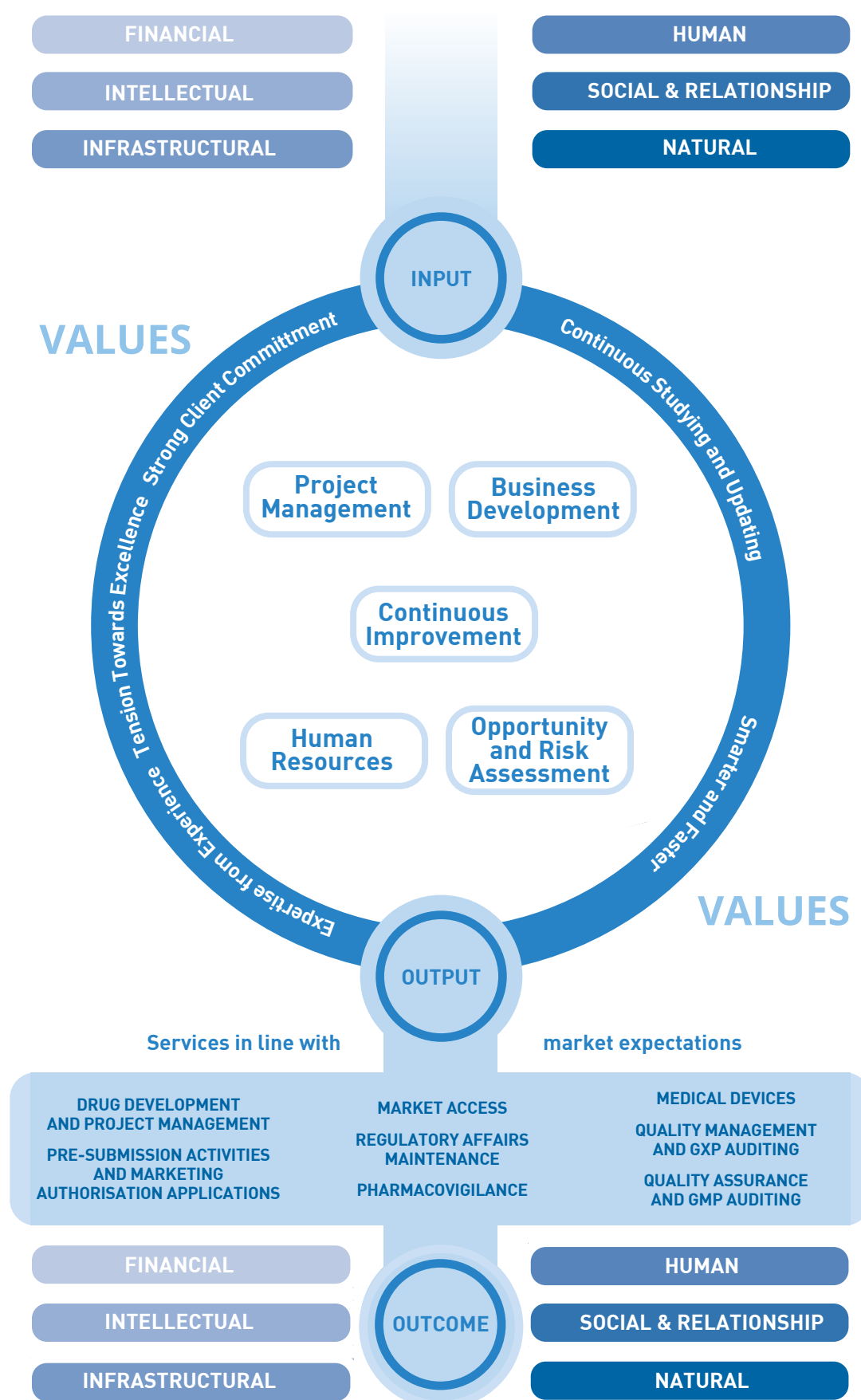


Social capital – The relationships between an organization and all its stakeholders, including communities, governments, suppliers and customers.



Natural capital – The resources that cannot be replaced and are essential to the functioning of the economy as a whole, such as water, fossil fuels, solar energy and carbon sinks.

In order to face up and win the market challenge RPN business model is structured as below:



RISK MANAGEMENT



GRI 102-15

In 2022 RPN risk management path was based on the following five risk categories:

1. People and organisation
2. Financial and economic
3. Technology
4. Compliance
5. External Factor

The risk assessment process is embedded into the 'Continuous Improvement' process, which includes the following activities:

- Conducting internal audits and receiving audits from third parties;
- Collection of feedback information, passive and active;
- Carrying out the Risks & Opportunity Assessment exercise.

The risk assessment is carried out annually with a view to continuous improvement, for each business process. During the assessment carried out for the year 2022, risks and opportunities within each process were identified and analysed by the Quality Assurance staff, with the support of the Process Owners, in order to ensure the efficiency of the company's quality system.

The assessment was followed by appropriate actions aimed at minimising the risks and seizing the opportunities identified

STAKEHOLDER ENGAGEMENT

 GRI 102-40, 47

RPN continued on its path for a structured management of the relationship with its most important stakeholders which have been represented in this map:

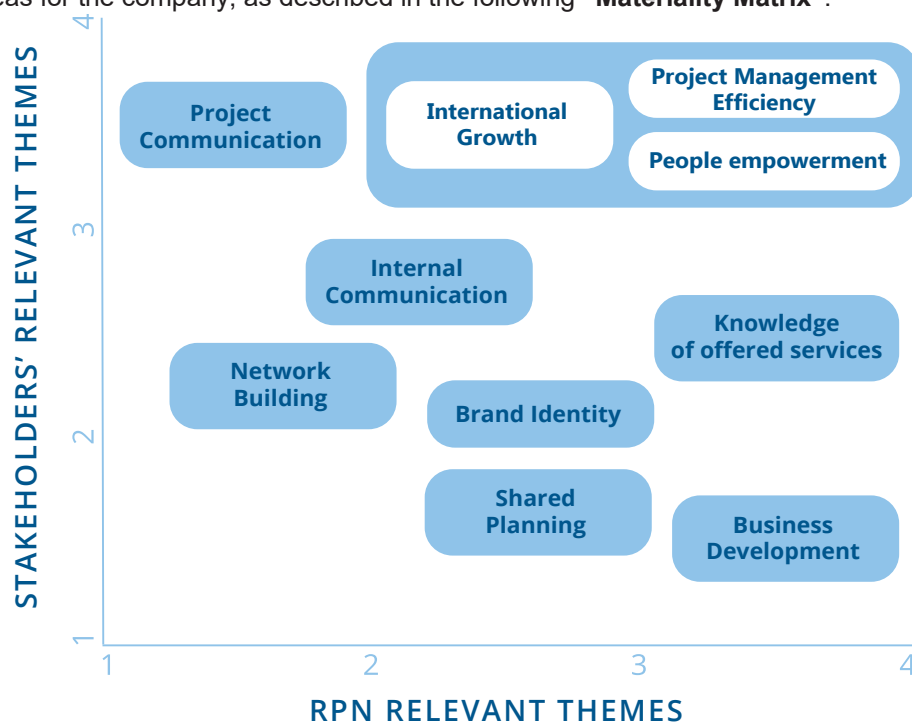
RPN STAKEHOLDERS MAP



Materiality is one of the inspiring principles of the framework <IR> that invites the companies to prepare their reports by focusing exclusively on aspects that affect in a significant way the ability to create value over the time, the so-called “material” aspects.

By aligning with this inspiring principle, RPN in 2022 leveraged on a specialized activity to collect new feedbacks that fostered the analysis of materiality carried out in 2021. This involves both the Company and its main stakeholders. The combined consideration of the internal and external relevance led to the identification of priority and most significant areas for the company, as described in the following “**Materiality Matrix**”:

RPN MATERIALITY MATRIX



RPN STRATEGY

RPN STRATEGY

2022 represented a successful year for RPN in terms of strategical results. The combined results of risk assessment and stakeholder engagement led the company keeping the strategic lines identified in 2020 as the following ones:

- International Growth
- Project Management Efficiency
- People empowerment

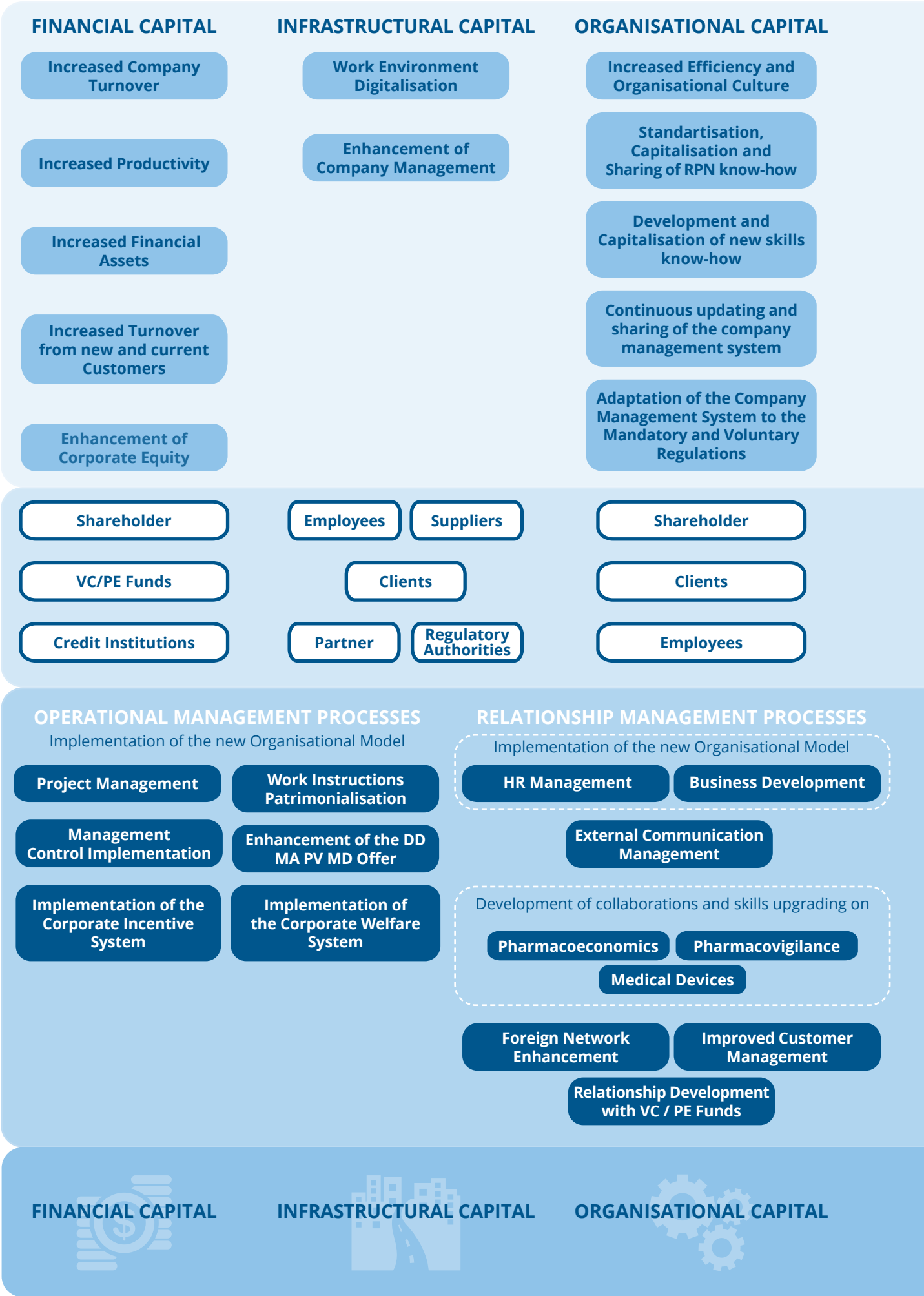
RPN's Strategic Map is constructed on a model that encourages an integrated definition of the strategy by reinterpreting the four traditional areas (Economic/Financial; Market; Organisational; Resources), to make them coherent with the IIRC framework:

- Impact generated on the six capitals
- Main stakeholders
- Processes involved
- Resources needed

This way, a comprehensive Integrated Strategic Map is obtained, reflecting the Integrated thinking concept that underpins the Integrated Report.

2023 Main Organisational Goals

- Implement specific business operations tailored to each process in order to achieve the objectives previously decided.
- Improving staff skills with regard to the management of the quality and information security system by increasing training
- Make the management of training on quality documents more efficient by integrating the document library with the training list and register
- Improve the internal know-how-sharing seminars among technical areas
- Commitment to the current customer base remains firm. A concrete value is recognized in the long-term relationships built



HUMAN CAPITAL

Increased Corporate Resource Commitment

Improvement of Communication, Collaboration and Internal Sharing

Enhancement of Resources' Skills

Increase in Corporate well-being and Strengthening of Corporate Culture

SOCIAL CAPITAL

Continuous Understanding of the External Context

Increased Market Shares

Enhancement of Corporate Communication

Improvement in Customer Management

NATURAL CAPITAL

Reduction of Company Activities Environmental Impacts

Maintenance of the Newest Energy Standards for the Company Headquarter

Employees

Competitors

Media

Universities, NFPs, Training and Scientific Companies

Clients

Local Authorities

Partner

Regulatory Authorities

Employees

Local Community

Local Authorities

INNOVATION PROCESSES

RPN Modern Workplace

Continued expansion of digitalization

RPN Academy implementation

Sharing Strategic Objectives with Resources

Integration of Corporate Management with the QMS and Business

Processes maintenance for GDPR compliance

Roll-out of a newly revised anticorruption procedure

Roll-out of newly revised internal processes to build on Social Media presence

REGULATION AND ENVIRONMENTAL PROTECTION PROCESSES

Facility Management

HUMAN CAPITAL



SOCIAL CAPITAL



NATURAL CAPITAL



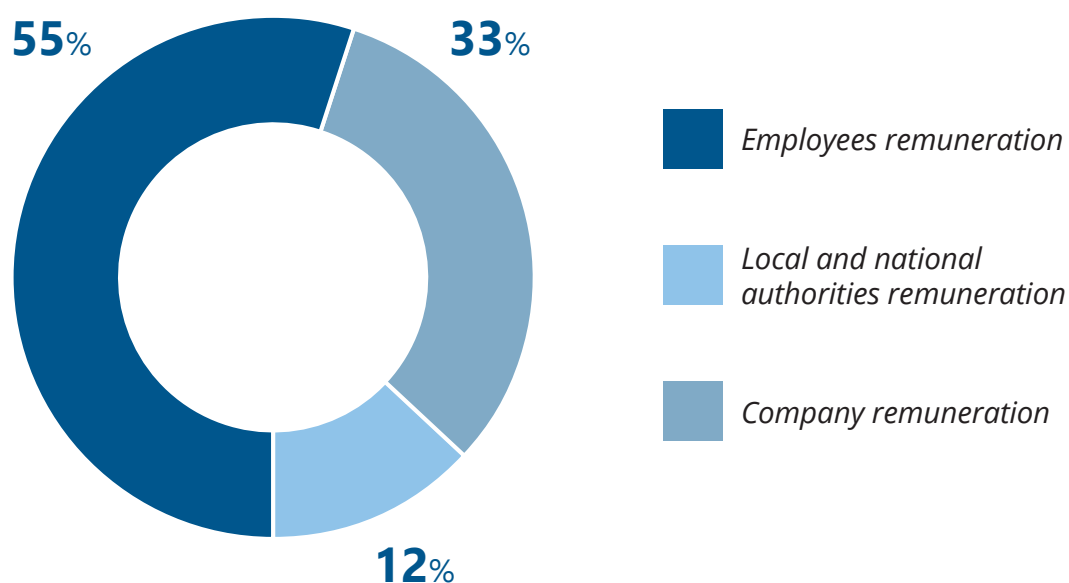
D. PERFORMANCE 2022

In the following chapter are reported the principal outcomes obtained by RPN during 2022 on each capital.



Highlights

1. Equity: **100%**
2. Net Financial Position: more than **2,500,000 €**
3. Turnover more than **5,800,000€**
4. Value distributed to stakeholders more than **5,000,000€**



ADDED VALUE DISTRIBUTED

RPN recognizes the importance of creating value for all its stakeholders and in 2022 distributed more than 5,000,000 € (following the 2021 path) divided as above.

In 2022, the accounting structure has been further structured within the company by leveraging on specific tools



ORGANISATIONAL CAPITAL

Following the insights emerged in 2021, the company continued to improve its organisational assets.

Following the implementation and maintenance of a ISO27001 certified Information Security Management System (ISMS), the ISMS Responsible Person runs a continuous supervision, development and control of the ISMS and to support the implementation of the related processes and initiatives. The cybersecurity tools and related procedures have been furtherly developed to keep meeting the industry standards and to keep awareness high across the whole personnel.

Management System

RPN is a ISO 9001:2015 certified company. A firm commitment is confirmed in delivering a high-quality level of services to the customers.

From the year 2021 RPN obtained also the ISO 27001:2017 certification for its Information Security Management System.

RPN digitalisation

The digitalisation journey of RPN continued through 2022. Support and training have been implemented with the aim to sustain and optimize the efficient use of the digital tools. The adoption of these systems has enabled the company to streamline information flows and processes, improving communication, archiving and document management.

In addition, RPN started building a strategic plan for the introduction of Artificial Intelligence tools.

INFRASTRUCTURAL CAPITAL



INFRASTRUCTURAL CAPITAL

RPN headquarter is designed to enhance employee well-being and organizational efficiency. Our team members made full use of the thoughtfully designed spaces provided at our premises, including variously sized meeting rooms, conference call facilities, and the Auditorium Room.

RPN Headquarter



HUMAN CAPITAL



HUMAN CAPITAL

2022, RPN initiated a strategic intervention to devise and implement an organizational model that gears RPN for further international expansion, while also fostering a business environment that functions smoothly across the different teams, with an emphasis on continuous improvement.

In parallel, RPN further improved the process for selecting and onboarding new staff. This is aimed at sustaining the growth that the company is having, while keeping the high level of expertise required.

A regular onboarding process is in place. This delivers to each of the new hire a set of induction trainings which include key aspects on the internal organization, the customer profile, the RPN quality and IT systems, project management and pharmacovigilance. As far as existing resources are concerned, the HR department conducts periodic interviews with all personnel aimed at monitoring the level of engagement and motivation and to allow all employees to express their opinions.

During 2022, a significant amount of effort has been dedicated to training.

Welfare services have been enhanced.

In addition, the use of smart-working during 2022 has been further improved becoming a structured practice

SOCIAL CAPITAL



GRI 102-43, 44



RPN continued to build on its Brand presence online through a Multi-Channel approach. Blogs and LinkedIn posts have been constantly published. The topics in scope covered all the RPN service areas, including Regulatory Affairs, Medical Device, Market Access, Pharmacovigilance and Drug Development. In addition, RPN continued successfully to leverage on the use of LinkedIn as a communication tool, with the aim of creating engagement and increasing visibility and brand awareness of the company.

The Stakeholder Engagement Path

In 2022 the path of Stakeholder Engagement has continued, with the aim to reinforce the relationship with its most relevant stakeholders by taking into consideration their needs and the themes relevant to them. All staff was kept aware on the value of sharing and funnelling insights gathered on market trends and stakeholders. Those have been analysed to provide inputs to the RPN Management and be the basis for action on stakeholder engagement.

Client satisfaction

The 2022 Survey on the Client Satisfaction revealed data and information which are useful for RPN to monitor its performance in the market and to assess the level of satisfaction of its customers.

The vast majority of customers learnt about RPN throughout word of mouth, confirming that the company's reputation is a strength which provides a competitive advantage. This was generated thanks to the quality of service offered.

The level of trust placed in RPN is decidedly high. In particular the interviews demonstrated a level of satisfaction of 3.56 on a scale of 4. The key-strengths acknowledged to RPN are: the ability to provide a quality service, the high professionalism, the customer orientation, the high level of collaboration and reliability. These results substantially confirm last year's results. A figure which confirms the growth of the RPN brand and how the brand itself is becoming a reference point in the mind of the customer.

Some minor improvements were suggested from customers, for which RPN will dedicate effort to make better and better, as part of its continuous improvement approach.



Memberships and Partnerships

In 2022, RPN continued to actively contribute to stakeholders' associations (e.g. Assobiotec, EUCOPE, ISPOR), including delivering speaking sessions.

Additionally, RPN has further developed its long-standing partnerships with regulatory and market access service providers located across EU/US with a deep understanding of the local landscape.

PHAROS

In order to strengthen its presence in the Market Access area, RPN continued its collaboration across 2022 within the Pharos Network, a highly specialised consulting network of renowned agencies in Europe.

Leveraging on synergies and teamwork, the Network takes care of introducing new drugs in Europe according to European regulations, to then decline everything according to the legislation of the different countries. In fact, it can support companies with efficient, key-in hand Pricing and Market Access services that are recognised as creative, focused, valuable and excellent.

The Network service offerings are wide and spread:

- Strategic analysis of environmental information
- EU-4 + UK market access and pricing strategies
- Requests for advice meetings with HTA and regulatory agencies
- Evidence generation and review
- Reimbursement file submissions
- Scientific (MA) Dossier writing
- Stakeholder engagement plans and activities (sounding boards, campaigning etc.)
- Pricing research & value demonstration services
- Cost-effectiveness modelling
- Price negotiation support
- Contracting with payers
- Wholesale license and distribution
- Listing in transparency lists
- Early Access Programs
- Collection and analysis of real-world evidence
- Multicriteria Decision Analysis (MCDA)



The objective of minimizing the use of paper was continued through 2022. Use of digital processes was further incentivized across all the internal functions.



E. OUTLOOK

The results obtained during the year and the management methodology adopted allowed the company not only to constantly monitor the realisation of the strategic objectives for the current year, but also helped to identify future objectives.

The company objective for 2023 is to sustain its growth in turnover by leveraging on the contribution of all services areas.

RPN will continue to pursue its internationalization process aimed at increasing the company's expansion towards new international customers and projects.

At the same time, the commitment to take care of the current customer base will remain the same, paying attention to the needs and level of satisfaction. In this regard, RPN confirms its intent to keep a proactive and "problem solving" mindset in delivering its services to customers.

Furthermore, RPN will intensify its brand communication using a multi-faceted channel strategy, encompassing social media, company blogs, and emails, to enhance the brand's visibility and credibility among stakeholders.

In order to support the strategic business expansion envisioned for 2023, RPN initiated a specific project aimed to enhancing the focus of the whole organization on the main growth drivers identified.

Focus areas impacted include:

- Improve Organization: Develop and implement a more streamlined and efficient organizational structure to increase productivity and collaboration
- Enhance Client Centricity: Improve the customer management system to increase customer satisfaction and loyalty
- Strengthen People Strategy: Develop and implement a comprehensive talent management strategy to attract, retain and develop top talent within the organization.



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