# **INTEGRATED REPORT** 2020



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# LETTER TO STAKEHOLDERS

LETTER

# **LETTER TO STAKEHOLDERS**



By presenting the following Regulatory Pharma Net (RPN) 2020 Integrated Report, I have proudly decided to highlight a set of our skills and features to the stakeholders with the aim of showcasing RPN's transparency and way of working.

Over the course of my 30-year career, I have learned the importance of commitment, seriousness and innovation. Collaborating with people and achieving together professional accomplishments have also given me the right motivation to keep working with the same desire that I originally had but with new goals.

How do we create value? By focusing on the quality of the service offered to our customers. We pay a special attention which comes from a desire to maximize customer satisfaction and to respond promptly to every client's need.

At the same time our efforts point not only at achieving financial and economics results but first and foremost at building a solid relationship with employees by promoting their balance between work and personal life and then at creating and maintaining a strong collaboration with customers and partners.

From year to year, we voluntarily offer this report in the hope that it will become a good habit for all companies, thus contributing to the growth of transparency in an industry where transparency itself is recognized as a distinctive value recognizable as a competitive advantage.

Managing Director Anita Falezza

ETTER TO STAREHULDERS

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# ABOUT THIS REPORT METHODOLOGICAL NOTE



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 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). Said path allows RPN, in possible future evolutions, to be already structured in case of recourse to the capital market.

### 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 2019 fiscal year (January 1 - December 31).

### 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 June 24th, 2021 by the Board of Directors. It is available on the Company's website at **www.regulatorypharmanet.com**.





EQUITY

**NET FINANCIAL POSITION** 

TURNOVER

VALUE DISTRIBUTED TO STAKEHOLDERS

**CLIENTS** 

LOYALTY RATE QUALITY MANAGEMENT SYSTEM CERTIFICATION

AVERAGE TRAINING HOURS PER EMPLOYEE

**CUSTOMER SATISFACTION** 

**QUALIFIED SUPPLIERS** 

# 100% 📀

more than **4,500,000**€ €

more than 3,000,000€ (℃)

more than 120



ISO 9001:2015 🖗

120



100% ★

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# A. ORGANISATIONAL OVERVIEW

# CORPORATE IDENTITY

• Regulatory Pharma Net (RPN), founded in Italy in 1999, is today 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.

• As a partner of national and international companies, RPN supports the Life Science industry in the development, registration and marketing of Life Science products, with a strong vocation for international growth.

• RPN works along with the clients, complementing their skill sets and resources in the management of their projects and offering a unique insight optimising time to market. With a transparent and compliant approach, RPN pursues client needs and goals generating tailored and successful solutions. RPN bridges the communication gap between the companies and the competent authority by offering a strategic and operational support.

• RPN offers specialized and differentiated expertise in a single reality, generating a strategic vision which spans across the multiple aspects to be considered during the entire lifecycle of a medicinal or healthcare product.



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

- Tension towards excellence
- Expertise from experience
- Smarter and faster
- Continuous studying and updating

SOMETHING IS CHANGING

Strong client commitment

# SUSTAINABLE DEVELOPMENT GOALS 2030:

- 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.

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Throughout 2020, RPN has chosen to commit in particular to 7 Goals 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"



 Regulatory Pharma Net services span the entire lifecycle of a lifescience product, from pre-clinical right through to post marketing and cover all regulated areas:

- Development
- Global and Local Regulatory Affairs
- Pharmacovigilance
- Market Access
- Services are provided by a highly qualified and experienced staff who stay abreast of the most recent developments in their field.
- As a client-driven company, RPN services are flexible enough to be used for a complete outsourcing package or as just stand-alone services.

### DRUG DEVELOPMENT AND PROJECT MANAGEMENT DEVELOPMENT AND PROJECT MANAGEMENT

RPN has wide experience across all key elements required to build a robust product development strategy. Getting a new lifescience 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.

<ul> <li>Development Plan</li> <li>Third party Vendor Selection &amp; Management</li> <li>Scientific Advice PIP</li> </ul>	• Management of Registration Procedures • Response Documents	• Early Access Programs • P&R Strategy • P&R Dossier Preparation & Negotiation	<ul> <li>Overall Regulatory Maintenance Variations, Renewals</li> <li>Promotional Material &amp; Congresses</li> </ul>
DEVELOPMENT	MARKETING AUTHORISATION	MARKET ACCESS	MAINTENANCE
<ul> <li>Orphan Drug Application</li> <li>Clinical Trial Applications</li> <li>IMPDs INDs</li> </ul>	CTD Modules     E-CTD	Company Budget Pay Back     Pre-Launch	<ul> <li>Pharmacovigilance</li> <li>Medical Information</li> </ul>

# MARKET ACCESS 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 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 Management System certified by Certiquality S.r.l.



# C. BUSINESS MODEL AND STRATEGY

# 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 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 2020 RPN risk management path was based on the following five risk categories:

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

The risk assessment is carried on at least once per year with the Process Owners with a view to continuous improvement, in order to guarantee the supervision of the quali-ty control of all the Process Owners and to make all the resources aware of the issues related to company quality. The inputs deriving from the analysis of risks and oppor-tunities have been elaborated and applied in the 2020 strategic map.

### Highlights Risk Mitigation Plan 2020

- Improvement of digital tools, including content management system (Office 365 and SharePoint)
- Improvement of accounting and administrative systems
- Improvements to the project management status tracking system
- Continuous customer focus improvements in order to optimize the support provided to the clients
- Increased level in the dematerialization (migration of documents from paper to electronic)
- Participation to thematic working groups
- Sharing of company goals and objectives-system implementation
- People empowerment and collaboration platforms implementation
- Coaching for soft skills development
- International network focus expansion

# STAKEHOLDER ENGAGEMENT



GRI 102-40, 47

RPN continued on its path for a structured management of the relationship with its most important stakeholders (see chapter D. Performance 2020, Social Capital for more details), which have been represented in this 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 led over 2020 an analysis of materiality which involved 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 STRATEGY

2019 was a positive year for RPN. The combined results of risk assessment and stakeholder engagement led the company to evolving the strategic lines identified in 2018 into 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.

### 2020 Main Organisational Goals

- Increased efficacy of external trainings with a specific focus in improving the learning via digital channels
- Continuous improvement of electronic documentation related to the Quality Management System and its related documents and trainings
- Development of the company welfare plan aimed to provide its employees further economic benefits
- It is confirmed the strategic intent to support the internationalization process of the company, aimed at increasing the expansion of the company towards new customers and projects worldwide
- Commitment to the current customer base remains firm. A concrete value is recognized in the long-term relationships built



**Outcome:** 

Projects, Processes and Organisation

nput:



# ERFORMANCE ERFORMANCE EDEODRANCE

# **D. PERFORMANCE 2020**

In the following chapter are reported the principal outcomes obtained by RPN during 2020 on each capital.

# PERFORMANCE PERFORMANCE PERFORMANCE



### Highlights

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



RPN recognizes the importance of creating value for all its stakeholders and in 2020 distributed more than  $3,000,000 \in$  (following the 2019 path) divided as above.



# ORGANISATIONAL CAPITAL

Following the insights emerged in 2019, the desire to support the company's internationalization project has been followed up. In particular, the Management has developed a strategic partnership with the specific aim of proposing itself in the international scene, with a focus on the United States.

Continuity was given to the commitment to develop and capitalise on the know-how of new skills. In 2020 a 64-hour training course on Project & Client Management was activated for all technical staff, aimed at perfecting project governance and client management skills.

Transversal working groups have been strengthened on various topics, including clinical trials, promotional material and regulatory activities to streamline the management of communications with customers. 21 internal seminars were held in order to share

experiences and training topics for all resources.

### Management System

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

### **RPN digitalisation**

Due to the Covid-19 pandemic, starting from the early 2020, RPN decided to let the employees work from home adopting the security protocol enhanced by the Italian MoH.This extraordinary situation confirmed the ability of RPN to go fully digital and to face a digital daily workload remote interactions internally and externally. It represented one more reason to confirm the willingness to keep a digital framework for processes and related documentation. The digitalisation journey of RPN continued also in 2020. 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 line with the defined digitalization plan, all across 2020 the implementation of SharePoint has been expanded to cover operational and nonoperational activities and processes across the different company functions, such as operations, administration, communication, marketing and HR. The use of SharePoint was further enhanced by implementing cross-functional flows between Business Development, the Operation Committee, technical staff and the administrative area.

### What's next

- Improvement of digital tools for Administration management
- Optimisation of the internal Enterprise resource planning (ERP) and increased link to the administrative system
- Further upgrades to the HR management digital platform.
- Sustain a solid Social Media brand presence



RPN started to benefit from the new corporate headquarter that is favouring the well-being of the people and the effectiveness of the organisation. All the employees were able to leverage on the designed areas of the new site, such as big and small meeting rooms, meeting rooms call conference set-ups, Auditorium Room.

### **RPN Headquarter**



### HUMAN CAPITAL

RPN has improved the process for selecting and onboarding new staff. This was aimed to sustain 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.

Plenary meetings have been also organized on a half-yearly basis in order to share results, objectives, changes and company performances. These are aimed also to maintain employees' engagement.

In line with the past years, RPN continues to work on building skills and competences. A specific plan has been kicked-off in order to improve the level of soft skills.

During 2020, a significant amount of effort has been dedicated to training. Employees attended overall more than 80 external and internal trainings and seminars. In addition, a structured training course has been implemented across the whole staff on Project, Client and Time Management. Additional training on project management skills is planned for 2021. An initial welfare package was introduced in January 2020, which includes also meal vouchers for all employees and a day off on their birthday. For 2021 it is planned to provide welfare amounts for all staff to be delivered through the use of a web platform. In addition, the use of smart-working during 2020 allowed staff to benefit from an improved work-life balance to which RPN intends to place greater emphasis during the future making it a practice that is detached from the pandemic.



RPN, following up on 2019, continued to build on its Brand presence online though a Multi-Channel approach. The RPN Blog received continuous updates as well as the RPN email newsletter plan. In fact, over the course of 2020, 38 articles were published on the company blog and 28 newsletters were sent. The topics in scope covered almost all the RPN service areas, including Regulatory, Medical Device and Market Access.

In addition, RPN continued to leverage on the use of LinkedIn as a communication tool, with the aim of creating engagement and increased visibility and brand awareness of the company.

### The Stakeholder Engagement Path

In 2020 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 2020 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 the quality of service offered.

The level of trust placed in RPN is decidedly high.In particular the interviewees demonstrated a level of satisfaction of 4.42 on a scale of 5. The key strengs 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 can be found in the following values.

When asked "How much would you recommend RPN to others?" on a scale of 1-10, the average response received is 9.

More specifically, customers broke down into the following categories:

- 24 promoters (i.e., who voted 9-10)
- 10 passive (i.e., who rated 7-8)
- 1 detractor (i.e., who rated 1-6)

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.



# P H ੈ R O S

In order to strengthen its presence in the Market Access area, RPN continued its collaboration across 2020 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-5 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)

# NATURAL CAPITAL

The use of digital systems for storing and sharing documents has resulted in a reduction in paper use of 1 kg per capita vs 2020.

# E. OUTLOOK

In light of a confirmation of its intention to continue with its approach geared towards continuous improvement and strategic business growth, for 2021 the company intends to focus on optimizing specific elements, including:

- Continued implementation and optimization of management control
- Continued analysis and optimization of the use of the company's management system for invoicing
- · Maintain focus and optimize planning and project management skills
- · Continue to invest in the training of its resources, both for soft skills and hard skills
- Continue to improve internal communication and employee involvement
- Implement the Welfare system
- Ensure efficiency and increase the added value deriving from networks and associations, both national and European, relating to services
- Continue to improve external communication with a multi-channel approach.

In 2021 it is planned to investigate the possibility of ISO 27001 certification, in addition to ISO 9001, to cover all the aspects related to the security of information managed by RPN.

As emerged from the objectives, particular attention will also be paid to the implementation of the Company's Welfare Plan across 2021, and the development of know-how within the organization.

As far as Business Development objectives are concerned, also for 2021 it is intended to sustain a growth in turnover, following the steady increase recorded in recent years. It is confirmed the strategic intention to support the internationalization process of the company, aimed at increasing the expansion of the company towards new customers and international projects.

At the same time, the commitment to take care of the current customer base remains firm in terms of long-term relationships, attention to needs and level of satisfaction, and proactiveness in offering additional services.

Finally, it is intended to follow up the external communication of the RPN Brand with a multi-channel approach, in order to amplify and strengthen the credibility of the RPN Brand towards the various stakeholders.

## CONTACTS

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# ED REPORT