

INTEGRATED REPORT

2019



Regulatory
Pharma
Net

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LETTER TO STAKEHOLDERS



GRI 102-1, 14

I am pleased to introduce this Integrated Report of Regulatory Pharma Net (RPN), which aims to provide to all our stakeholders an overview of the company activities and achievements of 2019. We continued to deliver on our goals on corporate identity, organisational model, digital transformation and employee empowerment. These are the key foundations that we defined and that we are committed to continue pursuing in the years to come.

I'm convinced that good results can be achieved only through commitment, transparency and innovation. Those are the main intangible elements that we have embedded in RPN way of operating. In the past, the underlying value of those elements has rarely been represented in a complete way, especially within the traditional company reporting systems.

In this Integrated Report we have found a structured way to showcase our ability to create value not only from an economic and financial point of view, but also in a way that is broadening up the perspective on elements such as:

- Quality of relationships with customers and partners
- Level of employees' empowerment and encouragement of work-life balance
- Ability to innovate the proposition of services and the organisational processes.

This non-financial disclosure effort is voluntary for RPN. We are confident that this practice will become a common standard for all companies, to contribute to the growth of a market where transparency and responsibility are increasingly recognised and valued as elements of competitive advantage.

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 is aimed to provide to stakeholders a fair, balanced and understandable assessment how the Company is creating value in the short, medium and long term from an economic, social and environmental point of view.

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.

This 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). Furthermore, it was deemed necessary the inclusion in the Integrated Report of information considered of major importance concerning some facts occurred after the end of the fiscal year and until the date of publication of this document.

The main sources of data and information indicated in the Integrated Report are:

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

The contents of the Integrated Report have been approved 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
1,300,000€

TURNOVER

more than
4,000,000€

VALUE DISTRIBUTED
TO STAKEHOLDERS

more than
2,900,000€

CLIENTS

more than
100

LOYALTY RATE

80%

QUALITY MANAGEMENT
SYSTEM CERTIFICATION

ISO 9001:2015

AVERAGE TRAINING HOURS
PER EMPLOYEE

more than
100

CUSTOMER SATISFACTION

4,3/5

QUALIFIED SUPPLIERS

100%



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, providing consulting through development, registration, launch and life cycle management of life science products.
- 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 offering, strategic and operational support.

CORE VALUES

CORE VALUES



GRI 102-16

The core values 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
- Strong client commitment

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 2019, 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

SERVICES OFFERED

“FROM RESEARCH TO MARKET”



GRI 102-2

- 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.

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.

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

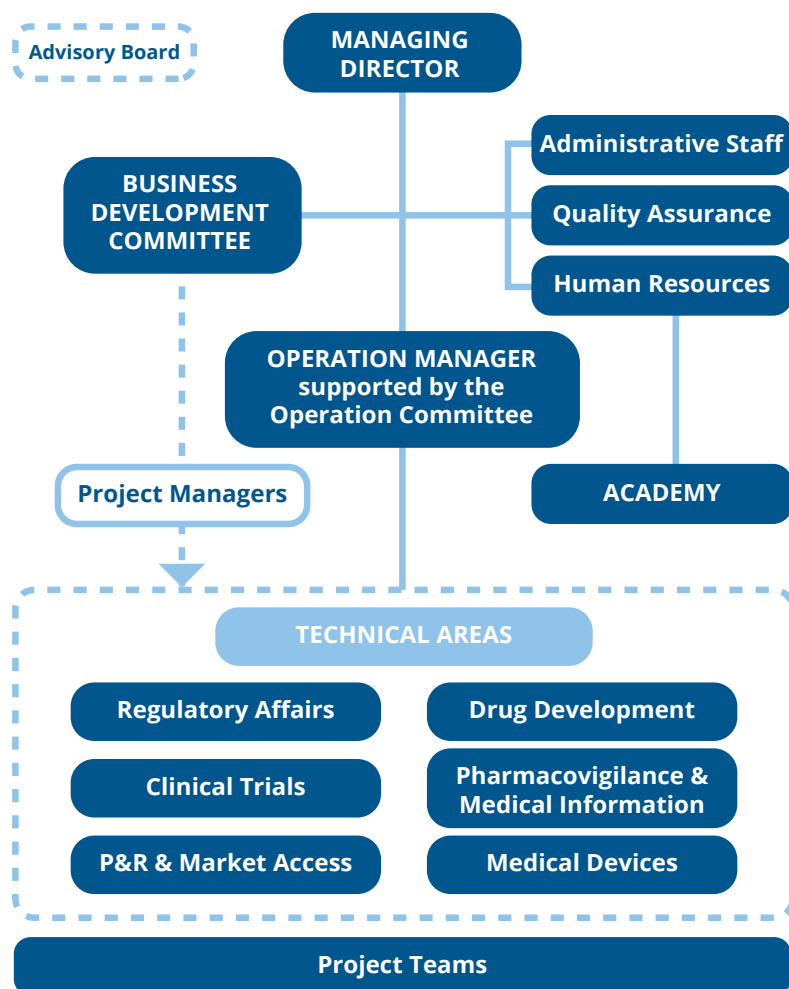
RPN team has a wide experience and a deep knowledge of GMP issues, with a record of successful projects supporting manufacturing companies.

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 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.

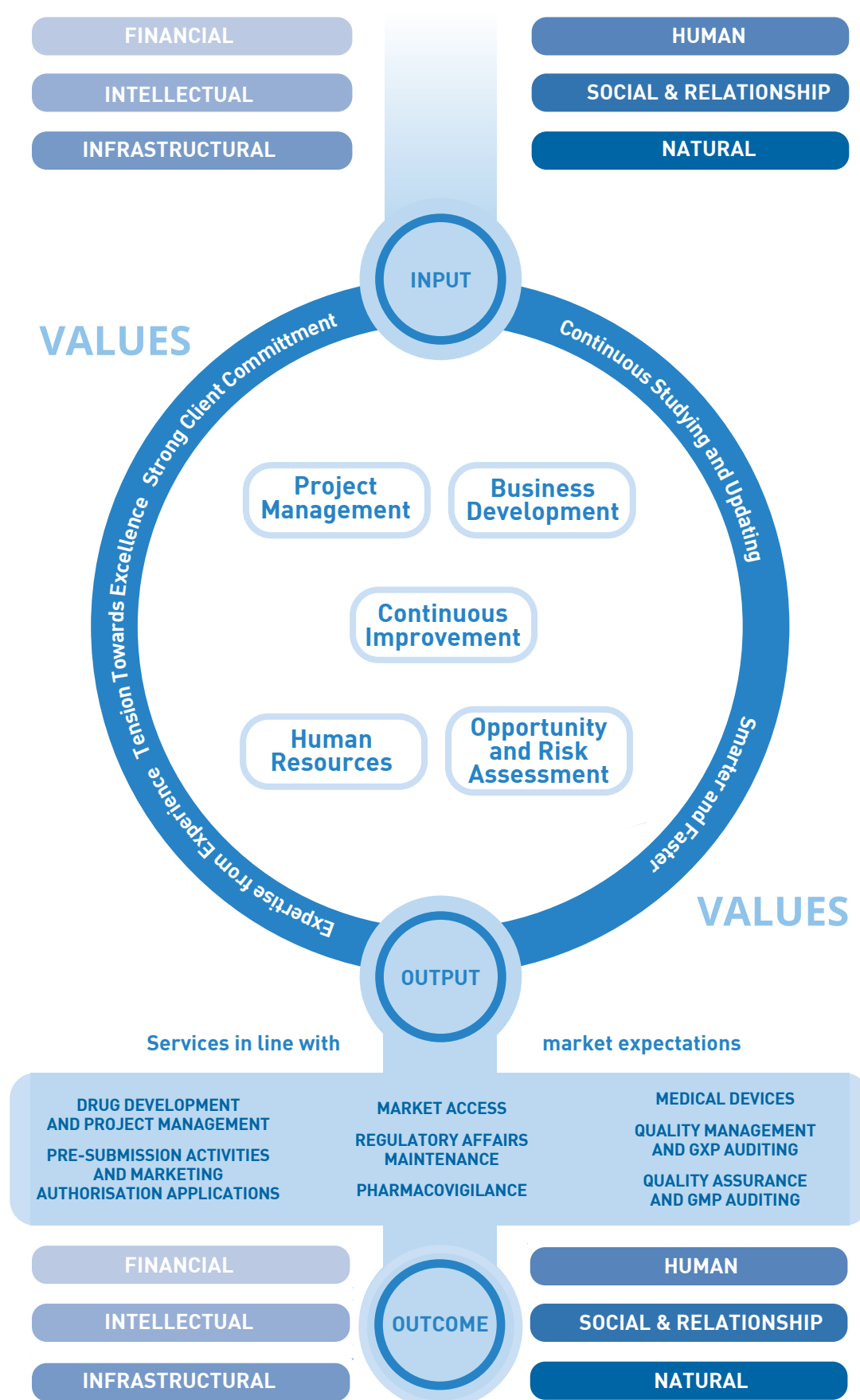


Social capital – The relationships between an organization and all its stakeholders, including communities, governments, suppliers and customers.



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 2019 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 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 quality 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 opportunities have been elaborated and applied in the 2020 strategic map.

Highlights Risk Mitigation Plan 2019

- Improvement of digital tools, including content management system (Office 365 and SharePoint)
- Improvement of accounting and administrative systems
- Improvements to the dedicated tool for project management status tracking
- Continuous improvements of the project teams in order to improve 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
- Unified communication and collaboration platforms implementation (Teams and Yammer)
- Coaching for soft skills development
- Market Access 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 2019, Social Capital for more details), which have been represented in this map:

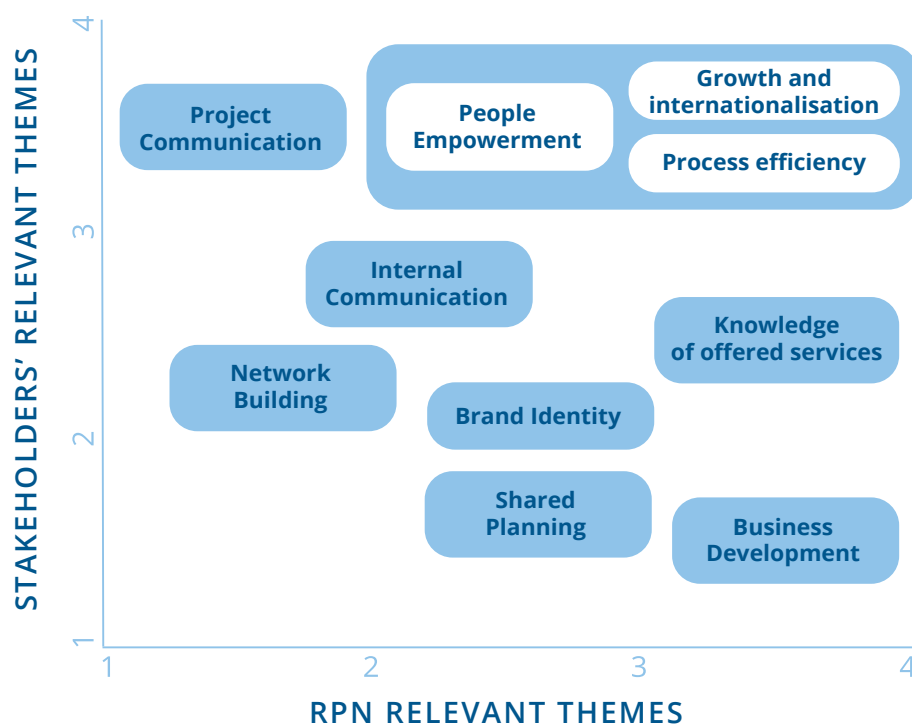
RPN STAKEHOLDERS MAP



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 led over 2019 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 MATERIALITY MATRIX



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

- Growth and internationalisation
- Process efficiency
- People empowerment

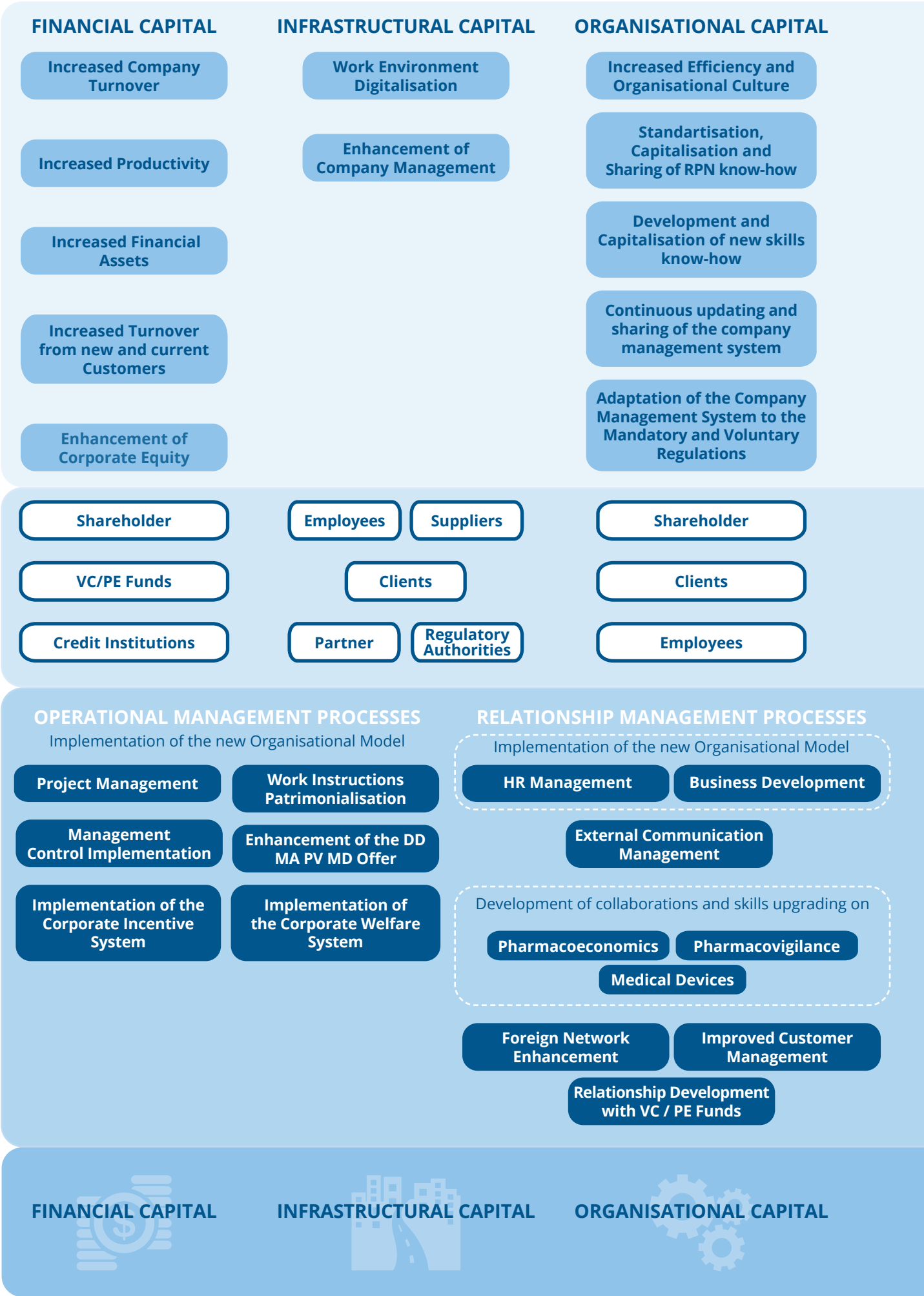
RPN's Strategic Map is constructed on a model that encourages an integrated definition of the strategy by reinterpreting the four traditional areas (Economic/Financial; Market; Organisational; Resources), to make them coherent with the IIRC framework:

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

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

2019 Main Organisational Goals

- Capitalization on the Project Management process previously implemented
- Continuous improvement of all operational activities in order to be more digitally efficient
- Fine tuning of the of SharePoint set of flows previously implemented
- Continuous improvement of the staff-related processes and activities



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

REGULATION AND ENVIRONMENTAL PROTECTION PROCESSES

Facility Management

HUMAN CAPITAL



SOCIAL CAPITAL



NATURAL CAPITAL





D. PERFORMANCE 2019

In this chapter are reported the main results obtained by RPN during 2019 on each capital.



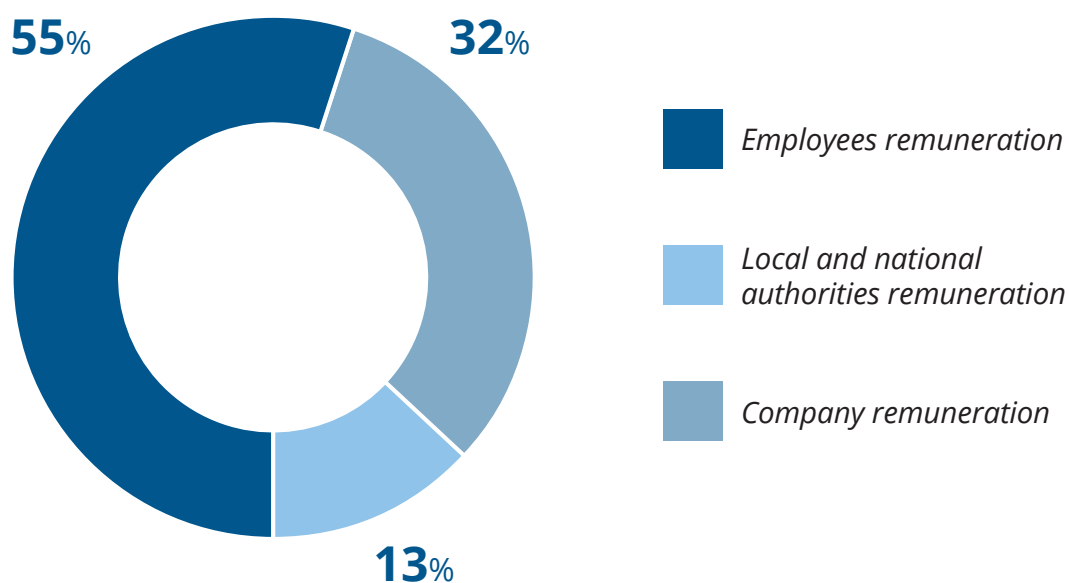
Highlights

1. Equity: **100%**
2. Net Financial Position: more than **1,300,000 €**
3. Turnover more than **4,000,000€**
4. Value distributed to stakeholders more than **2,900,000€**

The productivity improved by 14% during the year, calculated as the hours worked on customers compared to the total.

2019 was a positive year also in terms of relations with customers: in 2019 RPN had a total of more than 100 clients, of which approximately 80% were historical. This figure confirms the high level of customer loyalty that RPN generates.

As far as the geographical distribution of working hours is concerned, they are distributed in a balanced way among three geographies: Italy, Europe and extra EU.



RPN recognizes the importance of creating value for all its stakeholders and in 2019 distributed more than 2,900,000 € (+ 11,9% compared to 2018) divided as above.



ORGANISATIONAL CAPITAL

Management System

RPN is a ISO 9001:2015 certified company.

RPN digitalisation

The digitalisation journey of RPN continued also in 2019. 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 2019 the implementation of SharePoint has been expanded to cover operational and non-operational activities and processes across the different company functions, such as operations, administration, communication, marketing and HR.

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.



INFRASTRUCTURAL CAPITAL

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





The most significant change in Human Resources in 2019 involved the introduction of a professional HR Manager position with the aim of developing and coordinating activities such as: human resource planning, orientation, evaluation, recruitment and job security.

RPN's new HR Manager brought other capabilities in such as: organising employee job descriptions, determining roles and duties, analysing employee satisfaction and enhancing employee engagement.

In line with the past years, RPN continues to work on skills and competences: a soft skills assessment exercise was conducted to lay the foundations for the growth of each individual in a tailored way. Among the follow-up actions implemented, a designed and personalized training plan has been set up.

2019 saw the introduction of regular plenaries with the aim of bringing everyone involved in RPN together, and create a space where to discuss company goals, business operations, targets, business plans and to allow all employees to express their point of view.

20-years anniversary celebration



2019 marked the 20th Anniversary of our company. It was a milestone and what a good opportunity to look back on our growth, accomplishments and relationships built with customers and employees over the last two decades, but and more importantly, to look forwards.

As you can probably tell we decided that our 20th birthday was worth a little celebration or celebrating. We threw a party forgetting everything about emails, meetings and telephone calls, celebrating and drinking to our accomplished goals and our future.

We would like to thank everyone who has been involved and helped us reaching 20 years of success. Success that has been possible because of the support of our customers who rely on our services and our incredible team. A warm thank you to all of our customers, stakeholders, staff members who we share this success and look forward to carrying on this journey with.

Here's to yesterday. To 20 years of lessons learnt.

Here's to us and our history.

Here's to our wins.

Here's to our staff.

Here's to our clients, most of whom double as teammates and friends.

Here's to tomorrow. To the 20 years still to come, the clients we are yet to meet, the work we are yet to do.

SOCIAL CAPITAL



GRI 102-43, 44



Throughout the year RPN focused on strengthening corporate communication and continued with the systematic implementation of its blog and newsletter plan. During 2019 have been exactly published 34 blogs and 22 newsletters.

The Stakeholder Engagement Path

In 2019 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.

Client satisfaction

The Client Satisfaction Survey is part of the listening path conducted every year by RPN.

The research was conducted with the aim of collecting customer perceptions and detecting their satisfaction regarding the RPN services used during 2019; the results are aimed at identifying possible areas of weakness and planning the consequent corrective actions. The survey was proposed to 93 client companies and 35% of them replied.

The questionnaire investigated the following 6 macro topics:

- The image of RPN
- Knowledge of RPN services
- Satisfaction with the services used
- The level of trust in RPN
- The weaknesses of RPN
- Prospects for activities with RPN

From the comparison with the results of the customer survey submitted last year it emerged that the general client satisfaction increased from 4.1 in 2018 to 4.3 in 2019 (scale from 1 to 5) and consequently clients reward RPN's commitment by appreciating its attention to the quality of services offered, the professionalism of its people and its reliability.

For its clients RPN means:



PHAROS

In order to strengthen its presence in the Market Access area, RPN continued its collaboration across 2019 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



In 2019, RPN focused on reducing environmental impacts of company activities: the use of digital systems for archiving and sharing documents has allowed the maintenance of stationery and paper consumption to be maintained in line with the previous year, although the employees have increased over the year.

- Resources consumption:
 - Per-capita paper consumption: 17 kg (vs 18 kg in 2018)



E. OUTLOOK

Three strategic pillars identified in 2019 (Growth and internationalisation; Process efficiency; People empowerment) are the basis for the creation of value strategy that RPN will undertake in 2020 and in the following years.

For 2020 the following main needs have been identified:

- Invest in a feasibility assessment on the internationalisation process
- Move forward with the assessment on the use of a new management software to harmonise administrative and operational management
- Continue to explore new solutions on analytical management control system based on cost / responsibility centres

The results obtained during the year and the management methodology adopted have enabled the company not only to constantly monitor the achievement of strategic objectives for the current year but have also contributed to identifying future objectives.

Data analysis and continuous process monitoring allow the creation of a virtuous circle, which feeds on itself: the verification and realisation of the objectives allows to generate new objectives in continuity with the corporate strategy, which at in turn it is designed, updated and applied to the annual strategic map.

For 2020, the company has identified the following macro objectives, broken down by capitals, precisely defining the objectives by role and by resource:

Financial Capital:

- Increased Corporate Control
- Increased Productivity and Job Order Control

Infrastructural Capital:

- Work environment digitalisation

Intellectual Capital:

- Increased efficiency and organisational culture
- Standardisation, capitalisation and sharing of RPN know-how
- Development and capitalisation of new skills know-how

Human capital:

- Increased Corporate Resource Commitment
- Improvement of Communication, Collaboration and Internal Sharing
- Enhancement of Resources' Skills

Social and Relationship Capital:

- Increased Market Shares
- Enhancement of Corporate Communication
- Improvement in Customer Management

Natural Capital:

- Reduction of environmental impacts

Layout and graphics





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