

INTEGRATED REPORT

2018



Regulatory
Pharma
Net

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LETTER TO STAKEHOLDERS

 GRI 102-1, 14

I am very happy to share our Integrated Report 2018: also this year we decided to let our stakeholders get a glimpse of our work to illustrate the transformation the company is facing.

As last year, we decided to present our results through the Integrated Report, a structured way, underlining our ability to create value not only in a structured economic and financial point of view, but in an “extended way” in terms of quality and solidity of relationships with customers and partners, ability to empower employees and capability to innovate our services and our organization.

This non-financial disclosure effort is still voluntary and we remark our hope that it will soon become a standard practice for all companies, to contribute to the growth of a market where transparency and responsibility are increasingly recognized and valued as elements of competitive advantage.

In the future we are going to broaden further the business opportunities and generate value and well-being to share, by maintaining a responsible and sustainable vision of the development, with reference to our business growing plan.

That is how we want to look into the future, along with our stakeholders, to face imminent challenges and achieve even better results, always in tune with our mission.

Managing Director
Anita Falezza

ABOUT THIS REPORT METHODOLOGICAL NOTE

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

Regulatory Pharma Net S.r.l. (RPN) voluntarily publishes for the second consecutive year its Integrated Report aimed at providing to stakeholders a fair, balanced and understandable assessment on 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 concerns Regulatory Pharma Net S.r.l. and refers to the 2018 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 on 25/07/2019. It has been printed and is available on the Company's website at www.regulatorypharmanet.com.

HIGHLIGHTS

 GRI 102-7

EQUITY

100% 

NET FINANCIAL POSITION

more than
1,000,000€ 

AVERAGE TRAINING HOURS
PER EMPLOYEE

more than
80 

TURNOVER

more than
3,300,000€ 

CLIENTS

119 

LOYALTY RATE

80% 

VALUE DISTRIBUTED
TO STAKEHOLDERS

more than
2,600,000€ 

CUSTOMER SATISFACTION

4,1/5 

QUALIFIED SUPPLIERS

100% 

QUALITY MANAGEMENT
SYSTEM CERTIFICATION

ISO 9001:2015 

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



The core values that guide RPN 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 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 launched 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 2018, RPN has committed to 7 main goals:

-  **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 MOLECULE TO MARKET”



- Regulatory Pharma Net services span the entire lifecycle of a drug, from pre-clinical right through to post marketing and cover all regulated areas:
 - Drug 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 just as stand-alone services.

DRUG DEVELOPMENT AND PROJECT MANAGEMENT

DRUG DEVELOPMENT AND PROJECT MANAGEMENT

RPN has wide experience across all key elements required to build a robust drug development strategy. Getting a new drug 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 Orphan Drug Designation Applications and Scientific Advices.

PRE-SUBMISSION ACTIVITIES

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, 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



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 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.

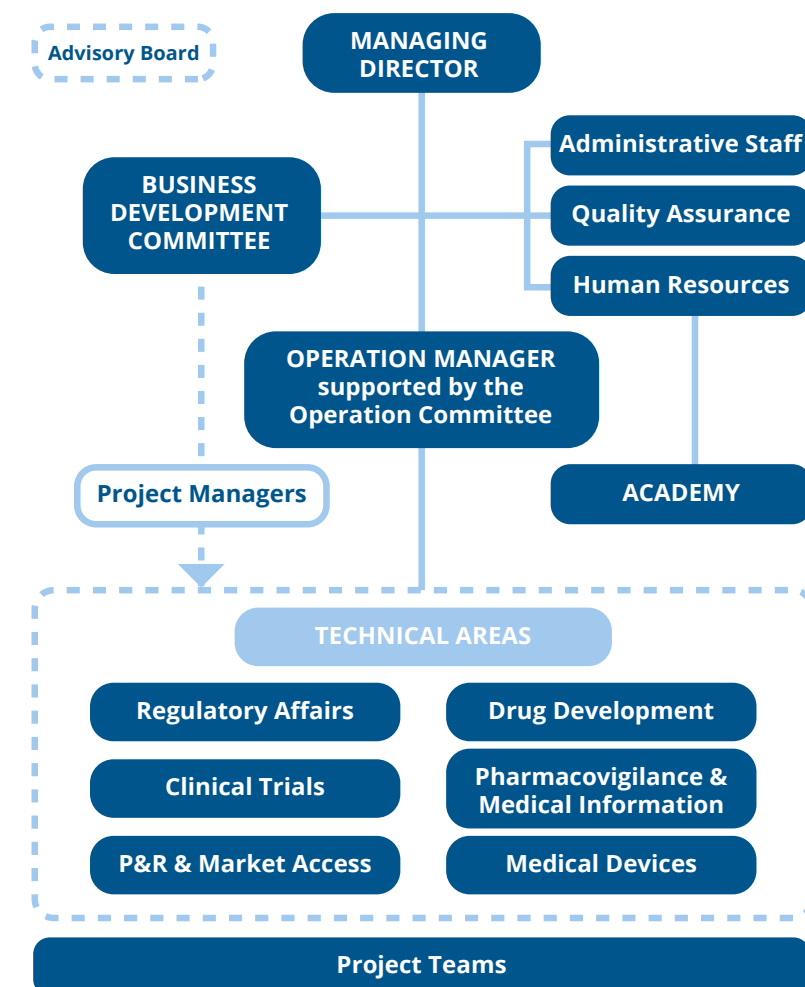
B. GOVERNANCE

ADVISORY BOARD

In 2018 the idea of setting up an Advisory Board to guide the internationalisation of RPN came about.

In 2019, the Advisory Board was established with an international scope and its members boast valuable finance and industry skills. Its purpose is to meet regularly to support and foster RPN process of growth and internationalisation.

ORGANISATIONAL STRUCTURE CHART



MANAGEMENT SYSTEM

RPN has a Management System certified by Certiquality S.r.l. The route to the certified Management System started in 2013 when the company obtained the ISO 9001:2008 certificate, which was upgraded to the ISO 9001:2015 in 2017.



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 – Developing Financial Capital for RPN means making an effort to guarantee a suitable amount of financial resources to accomplish its goals and distribute value to its stakeholders.



Infrastructural capital – Improving Infrastructural Capital for RPN implies giving to its people a headquarter suited to their needs, in which they can work well, safely and in harmony.



Organisational capital – Enhancing the Organisational Capital for RPN means committing to improve the organisation of its processes, making them more and more innovative, based on collaborative technologies and suited to the new market needs.



Human capital – Developing Human Capital for RPN means enhancing its people's competencies and capabilities through paths of professional growth and foster their motivation to improve and innovate.



Social capital – Increasing the Social and Relationship Capital for RPN means committing to establish and consolidate relationships with both national and international companies and institutions to create communities in which sharing value and strengthen the link with its stakeholders.



Natural capital – Improving Natural capital for RPN means limiting daily energy and resources consumption, primarily water, plastic and paper.

STAKEHOLDER ENGAGEMENT

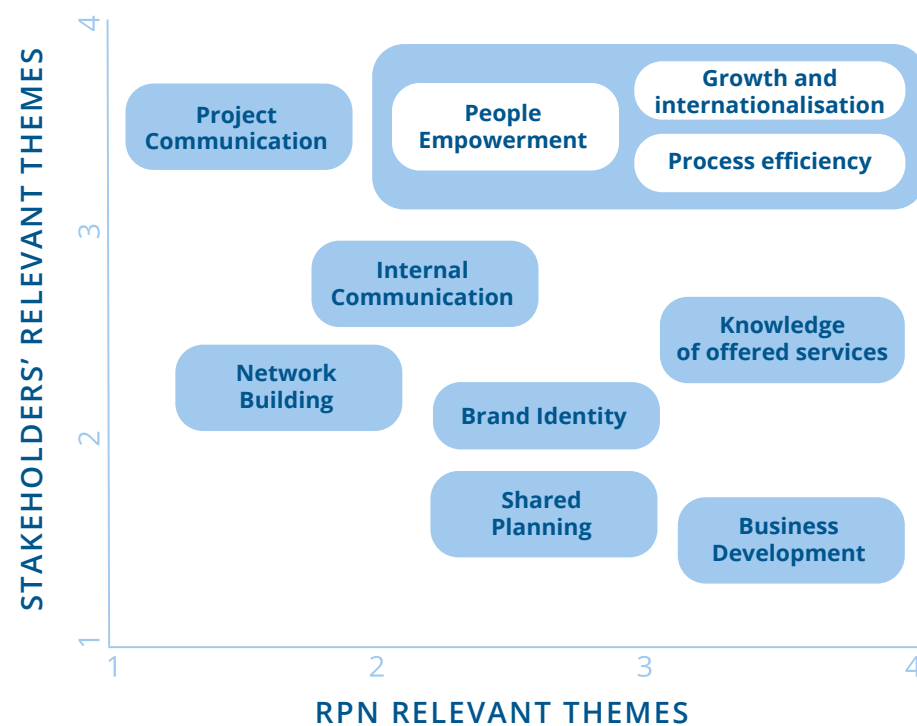
 GRI 102-40, 47

In 2017 RPN implemented a path for the structured management of the relationship with its most important stakeholders (see chapter D. Performance 2018, 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 2018 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

2018 was a highly positive year for RPN. The combined results of risk assessment and stakeholder engagement led the company to evolving the strategic lines identified in 2017 into the following ones:

- Growth and internationalisation
- Process efficiency
- People empowerment

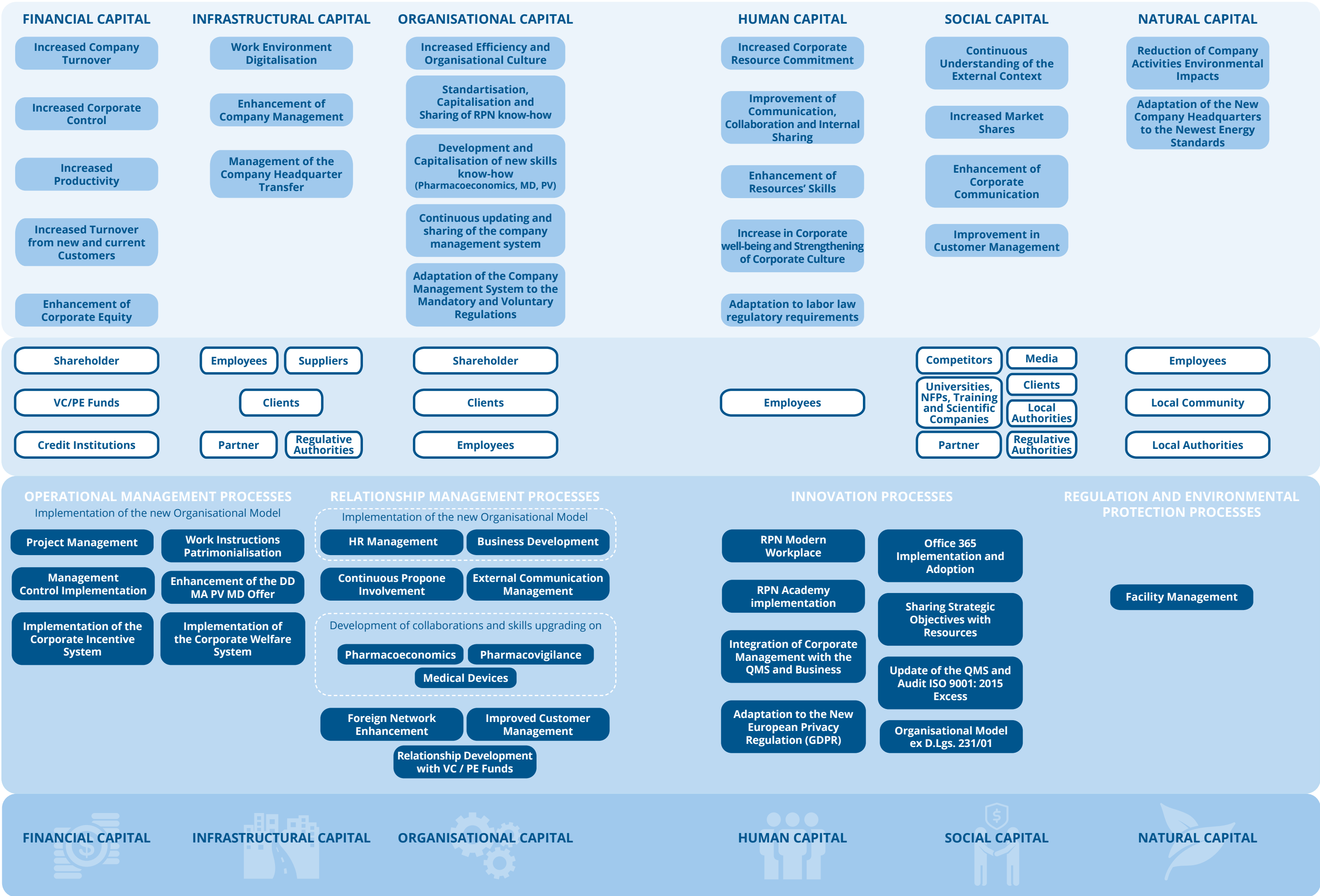
For the second consecutive year, RPN strategy has been represented according to the Balanced Scorecard methodology. RPN's Strategic Map still follows the basic BSC logic, but it is constructed on a model encouraging an integrated definition of the strategy by reinterpreting the four traditional areas (Economic/Financial; Market; Organisation-al; Resources) proposed by the BSC, 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, perfectly reflecting the Integrated thinking concept that underpins the Integrated Report.

2018 Main Organisational Goals

- Development of the PM process
- Implementation of the SharePoint system on all operational activities
- Implementation of SharePoint flows
- Dematerialisation
- Change of the operational headquarters
- Engineering of staff bodies
- Adjustment to the new fiscal instrument (electronic invoicing)





Highlights

1. Equity: **100%**
2. Net Financial Position: more than **1,000,000 €**
3. Turnover more than **3,300,000€**
4. Value distributed to stakeholders more than **2,600,000€**

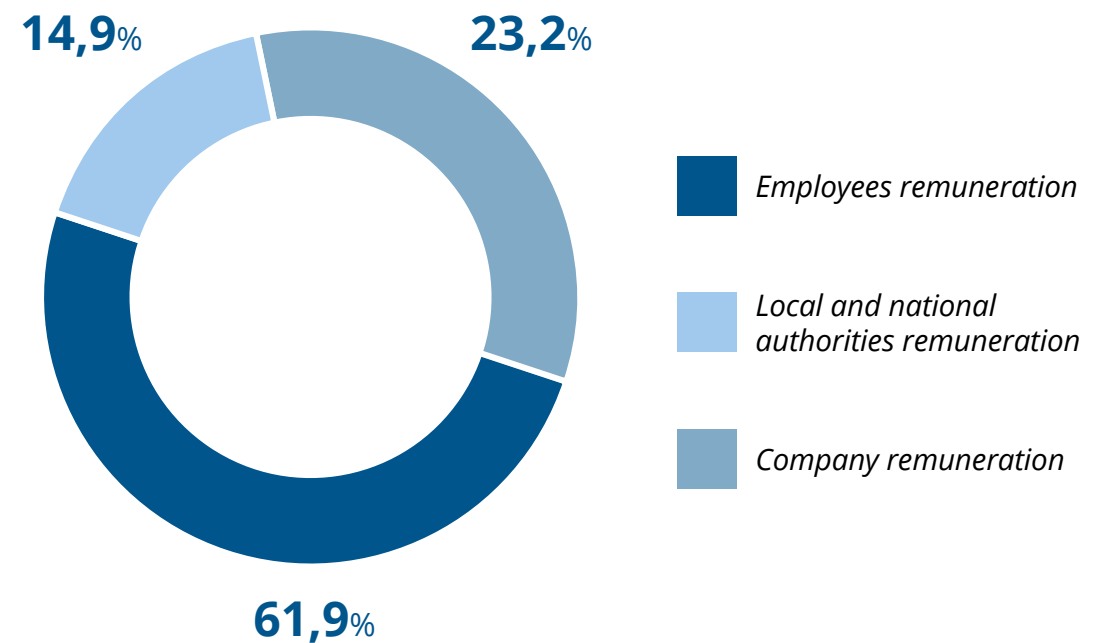
As far as the geographical distribution of working hours is concerned, they equally distributed among three areas: Italy, Europe and extra EU.

The productivity improved by A 5,8% during the year.

2018 was a positive year also in terms of relations with customers: in 2018 RPN had a total of 119 clients, of which approximately 80% were historical and the turnover from new clients was approximately 12% of the total.

RPN recognises the importance of creating value for all its stakeholders, and in 2018 distributed more than 2,600,000 € (+ 7,4% compared to 2017) divided as follows:

- Employees remuneration: 61,9%
- Local and national authorities remuneration: 14,9%
- Company remuneration: 23,2%



D. PERFORMANCE 2018

In this chapter are reported the main results obtained by RPN during 2018 on each capital



ORGANISATIONAL CAPITAL

Management System

Migration to the new 2015 standard for ISO 9001 was successfully completed: on 6th March 2018 RPN obtained the ISO 9001:2015 certification by Certiquality S.r.l.

RPN goes digital: Office 365

During 2018 all the employees were trained for the use of Office 365 Suite and SharePoint. The implementation of these systems has enabled the company to streamline information flows and processes, improving communication, archiving and document management. More in detail, Yammer and Teams were used extensively, also in the mobile version. The former is used especially for internal communications, while the latter for projects management organisation.

During 2019 RPN has planned to implement the use of SharePoint also for non-operational activities (administration, communication, marketing, HR).

What's next

- Internalisation of the administrative process together with its related
- Optimisation of the internal ERP and link it to the administrative system;
- Upgrading and automating through new tools of the Management Control System;
- Upgrade of the personnel management platform. Reserved access to employees for payroll, unique certifications, etc.



INFRASTRUCTURAL CAPITAL

New Headquarter

Considering the organisational development of RPN during 2017 and the strategic development path undertaken in 2018 for the years to come, the Management has decided to transfer its headquarter, in order to expand the space available for company activities and to modernise the work spaces.

The new corporate headquarter has been designed following guidelines strategically oriented to the creation of a work environment that favours the well-being of the people and the effectiveness of the organisation:

- Management of spaces for "mood":
 - Rooms with workstations ("operativity")
 - Rooms dedicated to reflection and "concentration" (maximum 3/4 people)
 - Rooms with meeting tables and call conferences ("teamwork")
 - Auditorium Room ("public event / plenary"): space for around 50-60 seats, convertible for "non placé" events
 - Relax room: "informal" meeting and sharing place

- Plant and smart devices:
 - Ducted heat pump air conditioning system
 - Flat screens with dock-in station in meeting rooms;
 - Open WiFi for all the employees
 - Increase of digital communication systems (yammer..)

Building Site walking

The design and the realisation of the new Headquarter were subject to comparison and sharing with the people of RPN. In March 2018 the "Building Site walking" was conducted: a group activity in which all the employees were taken to the site of the new office.

Subsequently some Focus Groups were conducted and the participants were given the opportunity to express their opinion on the new office, sharing their observations and making suggestions to make it more suitable to their needs and preferences.



HUMAN CAPITAL



- 30 employees and collaborators
- more than 80 average per-capita training hours

The most valuable resource for RPN is its people, who are guided and inspired every day by RPN's culture and values. In order to motivate them and guarantee them a higher level of wellbeing at work, in 2018 RPN has introduced a company incentive system. It is based on role, operation and strategic goals and on people's soft skills. Moreover, in 2018 RPN focused on enhancing the skills of its employees.

During 2018 RPN has implemented the onboarding procedure of the new staff and has developed a constant verification of the training carried out by the employees on the individual work instructions, with an annual skills assessment. Furthermore, personal goals are monitored quarterly through the QuickScore platform and a feedback system based on face to face interviews.

In order to incentivise and trigger its people, RPN is working on the introduction of an Academy through which to provide onboarding courses for newly hired, ordinary training courses, refresher courses and internal training.

RPN Team Building

To foster the importance given to people, some activities were conducted for and with RPN employees during the year.

In particular, for the first time an outdoor training day was organised to strengthen the team spirit of a large group of employees. Indeed, 75% of RPN employees have been involved in a free-climbing activity on an equipped wall.

The training, designed with the company management, had the purpose of stimulating greater knowledge among people, going beyond the working relationships, which often do not let people know each other in depth. In fact, the activity slogan was "let's discover the resources and values of our colleagues".

The work done with the group showed a good level of positive energy, a high commitment for most of the people involved and the activity carried out was much appreciated by the participants.

The outdoor context seems to have allowed a good majority of people to express themselves by showing their potential, while others have confirmed some attitudes and behaviors typical of what they manifest in the company context. Generally speaking, the juniors showed more spontaneity compared to the seniors.

The outdoor day ended with a moment of debriefing and reflection on what happened during the climbing: people reread some of their behaviours thanks to the presence of the coach and trainer who brought the experience back to the daily dynamics.

In particular, Partners recognise to RPN:

- great relational competence in daily confrontations
- excellent skills in establishing relations at European level and in collaborating internationally
- good technical competence
- timeliness and respect of the times

Customers were asked what distinguishes RPN from other suppliers or other market players. 75% responded "customer attention", 58% indicated "service quality" and 42% indicated "company skills".

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 2018; the results are aimed at identifying possible areas of weakness and planning the consequent corrective actions. The survey was proposed to 66 client companies and 55% 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 survey it emerged that customers are highly satisfied with RPN (4.1/5) and that they reward RPN's commitment by appreciating its attention to the quality of services offered, the professionalism of its people and its reliability.

The level of trust that RPN reserves is decidedly high. The most significant elements for which RPN is recognised by its customers are "professional competence", "quality of services offered", "reliability" and "accuracy".

For its clients RPN means:



Throughout the year RPN focused on strengthening corporate communication, publishing a blog and a newsletter.

The Stakeholder Engagement Path

In 2017 RPN started a process of structured dialogue with its stakeholders. The path of Stakeholder Engagement continued throughout 2018, within the Organisational Development Project 2018. It was aimed at reinforcing the relationship with its most relevant stakeholders by taking into consideration their needs and the themes relevant to them.

Two categories of stakeholders were involved: 9 customers and 3 partners, through phone interviews.

Stakeholders showed good willingness to participate and interest in questions. Most appreciated the involvement and the interest shown by RPN.

The Pharos Network

PHAROS

To achieve the goal of increasing market shares, RPN worked on the creation of a European market access network, the Pharos Network. It is a highly specialised consulting network of 5 renowned agencies located in France, Germany, Great Britain, Italy and Spain, all with experience in delivering a winning launch across Europe at a fair price.

Through a systemic approach 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

During the year, 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. Another good practice is the introduction of a “plastic free” policy in the company headquarter, with the replacement of plastic bottles and cups with the water dispenser.

- Resources consumption:
 - Per-capita paper consumption: 18 kg vs 22 kg in 2017



E. OUTLOOK

Three strategic pillars identified in 2018 (Growth and internationalisation; Process efficiency; People empowerment) are the basis for the creation of value strategy that RPN will undertake in 2019 and in the following years.

For 2019 two main needs have been identified:

- Evaluate the use of a new management software to harmonise administrative and operational management
- Evaluate and possibly implement an 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, supported by the Balance Score Card, 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.

The company is currently actively working on 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

- Organisational Model for RPN development
- 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 Company Activities environmental impacts

Consulenza tecnico-metodologica



Grafica e layout





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