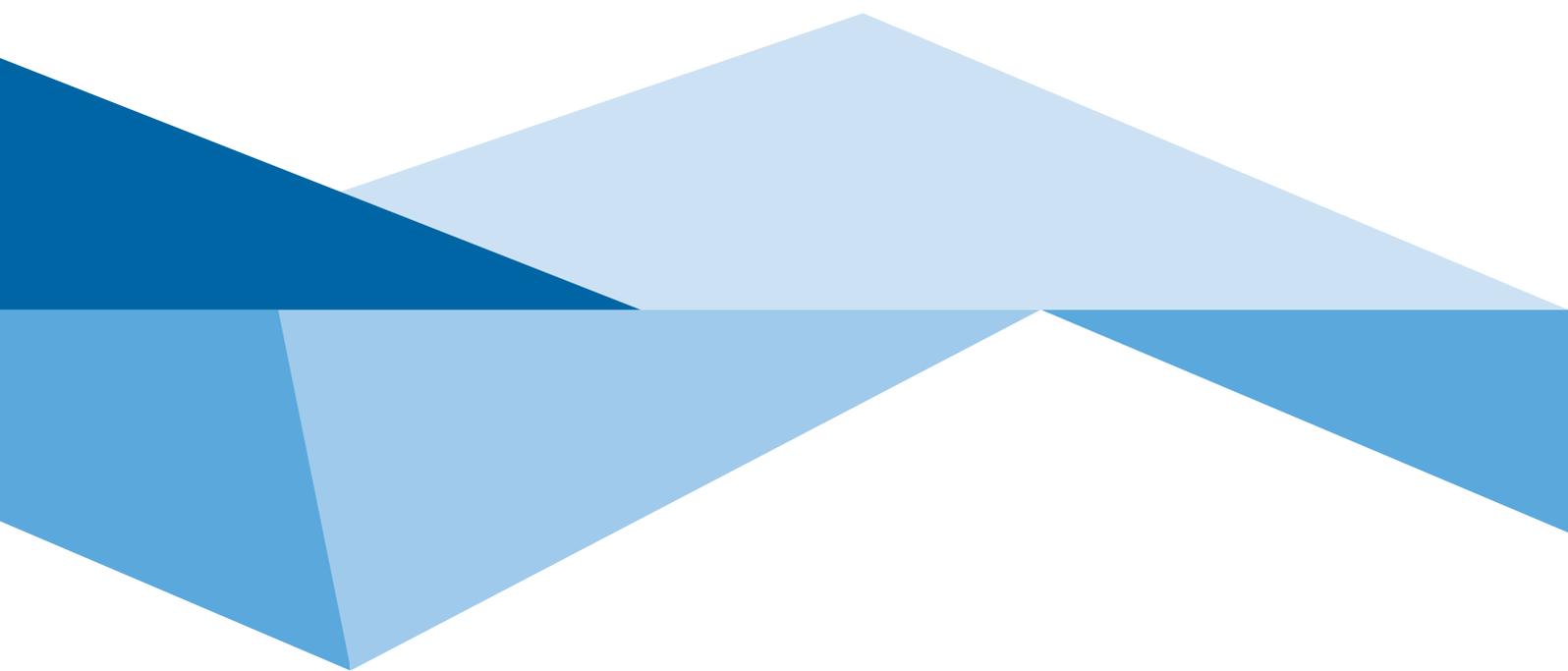


# INTEGRATED REPORT 2017



Regulatory  
Pharma  
Net

# TABLE OF CONTENTS

<b>LETTER TO STAKEHOLDERS</b>	<b>3</b>
<b>ABOUT THIS REPORT</b>	
<b>METHODOLOGICAL NOTE</b>	<b>5</b>
Highlights	6
<b>A. ORGANISATIONAL OVERVIEW</b>	<b>8</b>
Corporate Identity	8
Core values	9
Services offered	10
Organisational structure chart	15
<b>B. RISK MANAGEMENT AND STAKEHOLDER ENGAGEMENT</b>	<b>16</b>
Risk management	16
Stakeholder Engagement	18
<b>C. BUSINESS MODEL AND STRATEGY</b>	<b>20</b>
RPN Business Model	20
RPN Strategy	22
<b>D. PERFORMANCE 2017</b>	<b>24</b>
Financial Capital	24
Intellectual Capital	25
Infrastructural Capital	26
Human Capital	26
Social and Relationship Capital	27
Natural Capital	27
<b>E. OUTLOOK</b>	<b>28</b>

## LETTER TO STAKEHOLDERS

I am very proud to present this first Integrated Report of Regulatory Pharma Net (RPN), which aims to give a profile to all our stakeholders of a challenging journey that involved the company in 2017: a path of reflection on corporate identity, organisational model, digital transformation and employee empowerment, which will continue throughout 2018 and the years to come.

I have always thought, as my professional experience shows, that good results can be achieved only through commitment, seriousness, transparency, deepening and innovation.

They are all intangible elements, always embedded in RPN way of operating, but that in the past have rarely been represented in a complete way, especially within the traditional company reporting systems.

Finally, we have found the right tool to present, in a structured way, our ability to create value not only from an 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 to promote their balance

between work and personal life, and capability to innovate the content of services and the organisational processes: the Integrated Report <IR>.

This non-financial disclosure effort is now totally voluntary for RPN, but under the pressure of the normative evolution promoted by the EU, we hope it will soon become a standard practice 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.

**Anita Falezza**  
*Managing Director*



## ABOUT THIS REPORT METHODOLOGICAL NOTE

The Integrated Report is an information tool published annually and it is aimed at providing 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.

Regulatory Pharma Net Srl (RPN) started its journey towards Integrated Reporting at the beginning of 2017, and presents today its first Integrate Report, which is inspired by the "International Integrated Reporting <IR> Framework" issued by the International Integrated Reporting Council (IIRC).

This report has been structured to provide stakeholders with financial and non-financial information relevant to them and 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 report is also a first compliance effort, totally voluntary as RPN is a SME, on Italian Legislative Decree 254/2016 and Directive 2014/95/EU of the European Parliament and of the Council of 22 October 2014 amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large undertakings and groups.

The reporting scope concerns Regulatory Pharma Net Srl and refers to the 2017 financial year (January 1 - December 31). However, the Report includes information deemed to be relevant but regarding events occurring after the end of the financial year and up to the date of publication of this document.

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

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

The Integrated Report has been printed and is available on the Company's website at [www.regulatorypharmanet.com](http://www.regulatorypharmanet.com)

# HIGHLIGHTS

EQUITY

**100%**

NUMBER OF CLIENTS

**99**

**70%**

CUSTOMER LOYALTY RATE

TURNOVER MORE THAN

**3,000,000**

Euro

Quality Management System Certification

**ISO 9001:2015**

AVERAGE TRAINING  
HOURS PER EMPLOYEE  
MORE THAN

**70**

RESEARCH &  
DEVELOPMENT  
PROJECTS

**5**

VALUE DISTRIBUTED TO STAKEHOLDER: MORE THAN

**2,500,000**

Euro



# 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 authorities offering, strategic and operational support.

### Core Values

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



**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 and 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**

RPN has wide experience across all key elements required to build a robust drug development strategy. Getting a new drug, biologic or even a reshaped drug from the bench to market is a complex process that requires specific know-how in different areas. RPN offers a team to assist the client to plan Quality (Chemistry, Manufacturing and Control, CMC), Safety (Nonclinical), and Efficacy (Clinical) studies, working with the Client to design drug development plans that meet the current regulatory standards and align with the most

up-to-date thinking of Regulatory Agencies. 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 and Marketing Authorisation Applications**

RPN provides strategic and operational support for pre-submission activities in EU and US, being involved in many Scientific Advice procedures with EMA, FDA and National Competent Authorities; Orphan Drug Applications to EMA and FDA; Paediatric Investigation Plan (PIP)

applications; Pre-submission meetings; as well as in the 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 and has recently submitted many applications in EU (CP, MRP, DCP and National) and in the US (NDA, ANDA, BLA).

RPN Activities includes 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. While market approval is grounded on quality, safety and efficacy, Market Access is contingent upon additionally demonstrating cost-effectiveness to payers.

RPN, with a thorough knowledge of the local access landscape and of the stakeholders who shape it, has the capability to provide assistance in the definition of the P&R strategy, preparation and submission of the P&R dossier compliant with the local requirements and negotiation with the authorities to achieve a good deal. RPN has a marked 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, supporting them with any local pharmacovigilance activities, acting as 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 appropriate 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 and are interested in marketing their devices into the Italian territory or in the European Union.

RPN service portfolio includes but is not limited to contacts with Notified Bodies and implementation of the appropriate quality system, classification of borderline products, risk analysis, preparation of technical files and

revision of the technical documentation in order to obtain the CE mark.

RPN performs audits at companies and suppliers, identifies qualified laboratories to conduct tests on devices, supports in 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 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.

RPN supports clients to the implementation of the appropriate quality system (including quality system for manufacturers of medical devices, etc.), revision of the technical documentation and 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/maintenance of GMP certificates and manufacturing authorisations through quality and GMP gap analysis; GMP auditing; CAPA plan and support for contacts with the authorities.

### Tailored services for Start-ups

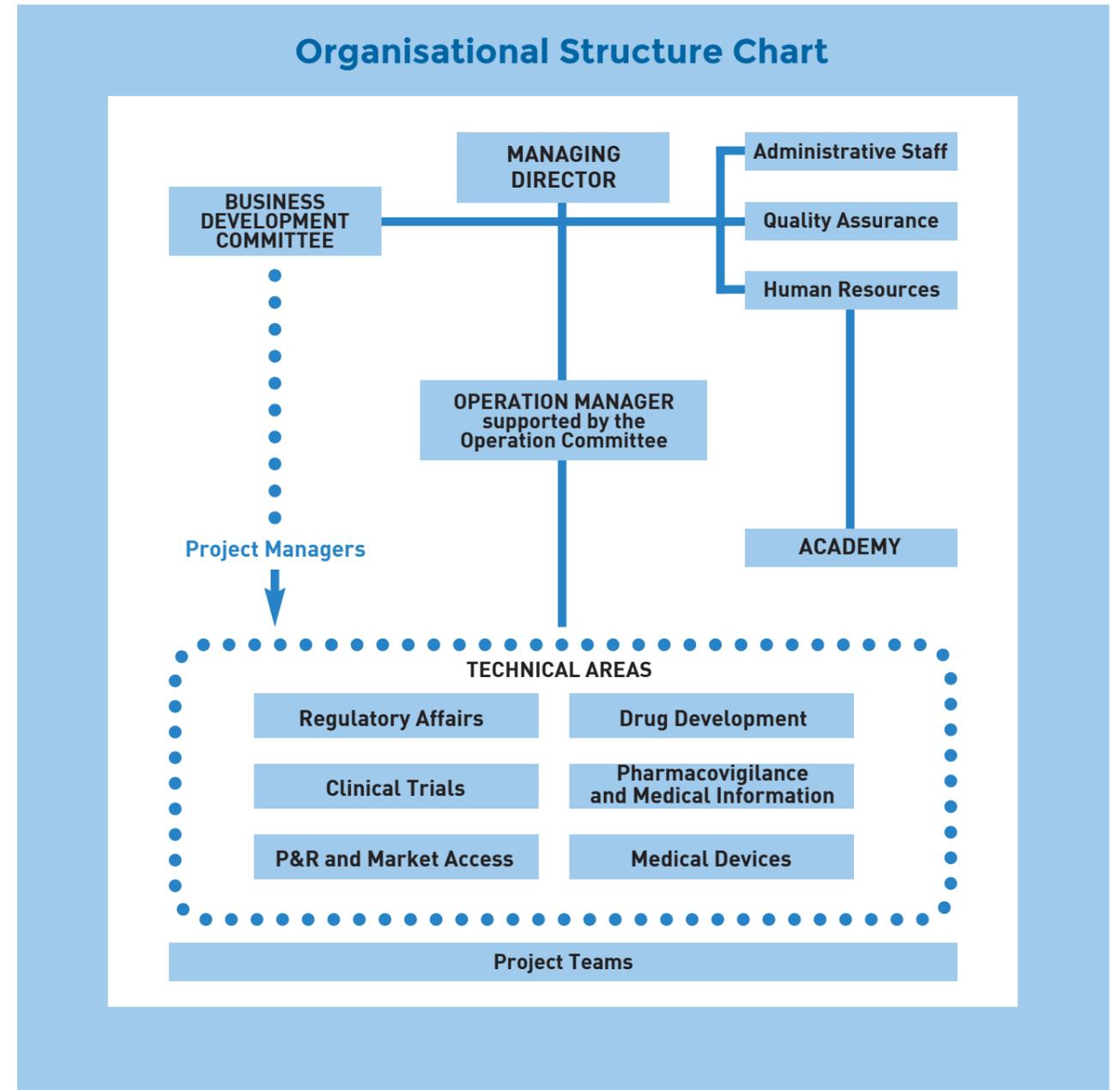
Starting an entrepreneurial activity is a complex, delicate process, affected by numerous factors. RPN has the experience to put together a package of integrated services, aimed at facilitating and speeding up the implementation of the business idea up to the market.

RPN is a company with the passion of growing, innovating and thinking of its clients' potential. RPN takes care of clients' projects, supporting them in all the activities and projects.

RPN is able to tailor the best strategy to develop a new product, a renovated product or a new medical device, puzzling all the required skills and competence to reach successfully the clients' goals and to maintain budget and timelines. RPN has know-how, contacts and expertise to reach and manage Contract Manufacturing Organisation, Contract Research Organisation, Key Opinion Leaders, and partners fitting with the specific need of a startup company.

### Regulatory Pharma Net Research and Development projects

RPN undertakes R&D projects in order to develop new services and procedures that will help in growing and expanding its operations. Systematic investments in R&D could provide big competitive advantages developing new services in the highly regulated and innovative pharmaceutical field. In 2017 RPN invested in 5 R&D projects aimed to improve the services offered and the internal tools for the management of the project.



### An important organisational innovation: "The Committees"

The RPN committees, established in 2017, represent a collegial way of managing the commercial aspects (Business Development Committee) and the operational aspects (Operation Committee).

- **BUSINESS DEVELOPMENT COMMITTEE (BDC)**  
BDC is the commercial development center of RPN

and is a purposeful, advisory and decision-making body, placed in staff to the Managing Director (MD).

- **OPERATION COMMITTEE (OC)**  
OC is the operational management center of RPN and is a proposing, advisory and decision-making body reporting directly to the Operation Manager (OM)

# B

## RISK MANAGEMENT AND STAKEHOLDER ENGAGEMENT

RPN competes in an extremely dynamic market, which is characterised by the following key drivers:

- Standardisation of services
- Concentration of pharmaceutical companies into larger group
- Increasing integration upstream and downstream of the supply chain
- Barriers to entry for new players
- Greater visibility on the market by large groups for greater contacts, resources and investment capacity
- Emerging role of startups

RPN is well aware of its need of having a complete vision of the context in which it operates, which is useful for the construction of its development strategy. This includes the market in which the organisation operates, the risks it may face, and the main stakeholders to which it must respond.

For this reason RPN in 2017 embarked on two different and strategic paths:

- **A Risk Management Assessment**
- **A Structured Stakeholder Engagement**

### Risk management

To successfully face the challenges that the market poses, it is crucial to be aware of one's risks, to be able to address them and, if possible, turn them into opportunities. This approach is consistent with the requirements of the ISO 9001:2015 certification (acquired by RPN in March 2018), whose Risk-based thinking approach is designed to be identified, considered and controlled by organisations in the design and use of the quality management system.

For this reason, in 2017 RPN embarked on a path of risk management in which it established a framework where important and emerging risks were identified, quantified and managed.

The risk framework is designed to address all the significant risks related to people and organisation, financial and economic, technology, compliance and external factor that could undermine RPN ability to achieve its business objectives in the future.

## Highlights of RPN General Risk Mitigation Plan

TRAINING ACADEMY  
TO ADVANCE SPECIALTY SKILLS

PROJECT MANAGEMENT RE-ENGINEERING  
TO MAKE THE PROCESS MORE EFFECTIVE

ENTERPRISE SOCIAL NETWORK  
TO ENHANCE CORPORATE COLLABORATION

INTERNATIONAL PARTNERSHIP  
NETWORK CREATION

NEW CUSTOMER SATISFACTION SURVEY

IMPLEMENTATION OF DIGITAL  
TRANSFORMATION IN BUSINESS PROCESSES

RPN implemented an Enterprise Risk Management consisting in Risk Assessment and objectives or mitigation plans setting:

### 1. People and Organisation

- Launch of a Corporate Training Academy to develop high level technical and soft skills
- Project Management Re-engineering to improve the efficiency and the quality of the offered services
- Making communication and collaboration more effective through innovative enterprise digital platforms

### 2. Financial and Economic

- Creating an international partnership network to expand the offered services and the market presence
- Enhancement of predictive capacity through a re-engineered forecasting and budgeting process
- New customer satisfaction survey to boost

relationship with clients and improve the quality of services thanks to an effective feedback system

### 3. Technology

- Digital Transformation processes to improve collaboration, data storage and corporate knowledge sharing
- Improving data security through the update of a Disaster Recovery Plan
- Digitalisation of the Corporate Quality Management System

### 4. Compliance

- Improving the internal procedures for regulatory updates
- Upgrade to the new European law on General Data Protection (GDPR)

### 5. External Factor

- Reorganising the Business Development Process to optimise its performances

### Stakeholder Engagement

RPN was committed in terms of empowering the relationship with all the internal and external actors who contributed in the value creation throughout 2017.

RPN started a path of Stakeholder Engagement aimed at reinforcing the relationship with its most relevant stakeholders in order to take into consideration their needs.

The purpose of the engagement was to start a structured dialogue between RPN and its stakeholders in order to:

- highlight the themes of common interest on which to develop mutual business strategies;
- identify innovative initiatives;

- consolidate relationships based on trust and transparency

Below the most relevant steps and outputs of the Stakeholder engagement path:

#### 1. Identification of RPN stakeholders:

This step consisted in the involvement of the leadership team through the Focus Group Methodology. As a result, the main RPN Stakeholders have been identified and positioned within the "Stakeholder Map", which identifies 4 different categories of Stakeholders:

- **Essential Stakeholders:** those who need to be involved because they highly influence RPN performance, and in turn they are highly influenced by it;

- **Interesting Stakeholders:** those who should be involved, as they could have a high influence on RPN performance but are not very influenced by it;
- **Weak Stakeholders:** those who are highly influenced by RPN but, in turn, have little ability to influence its performance;
- **Others:** those who do not significantly impact RPN performance and which in turn are not affected by it.

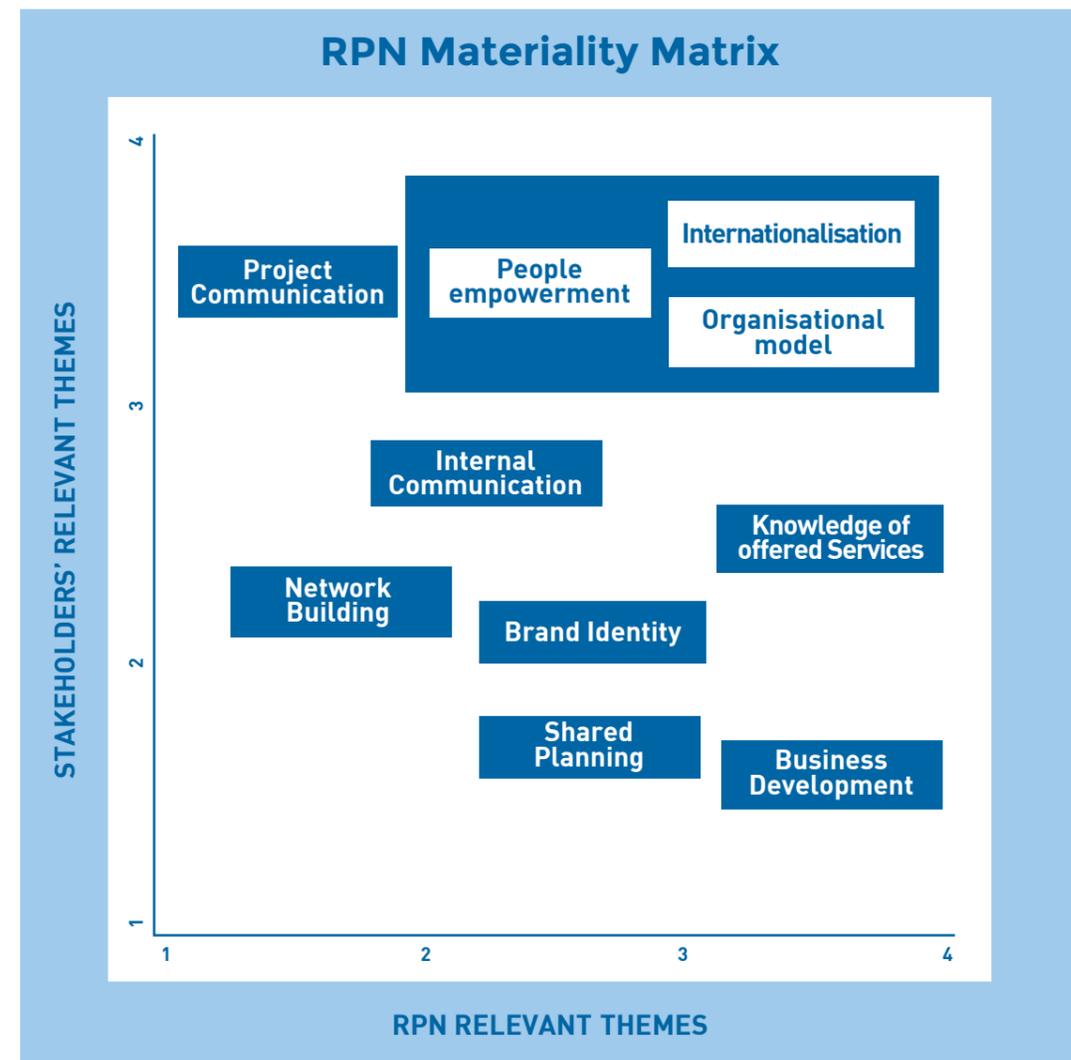
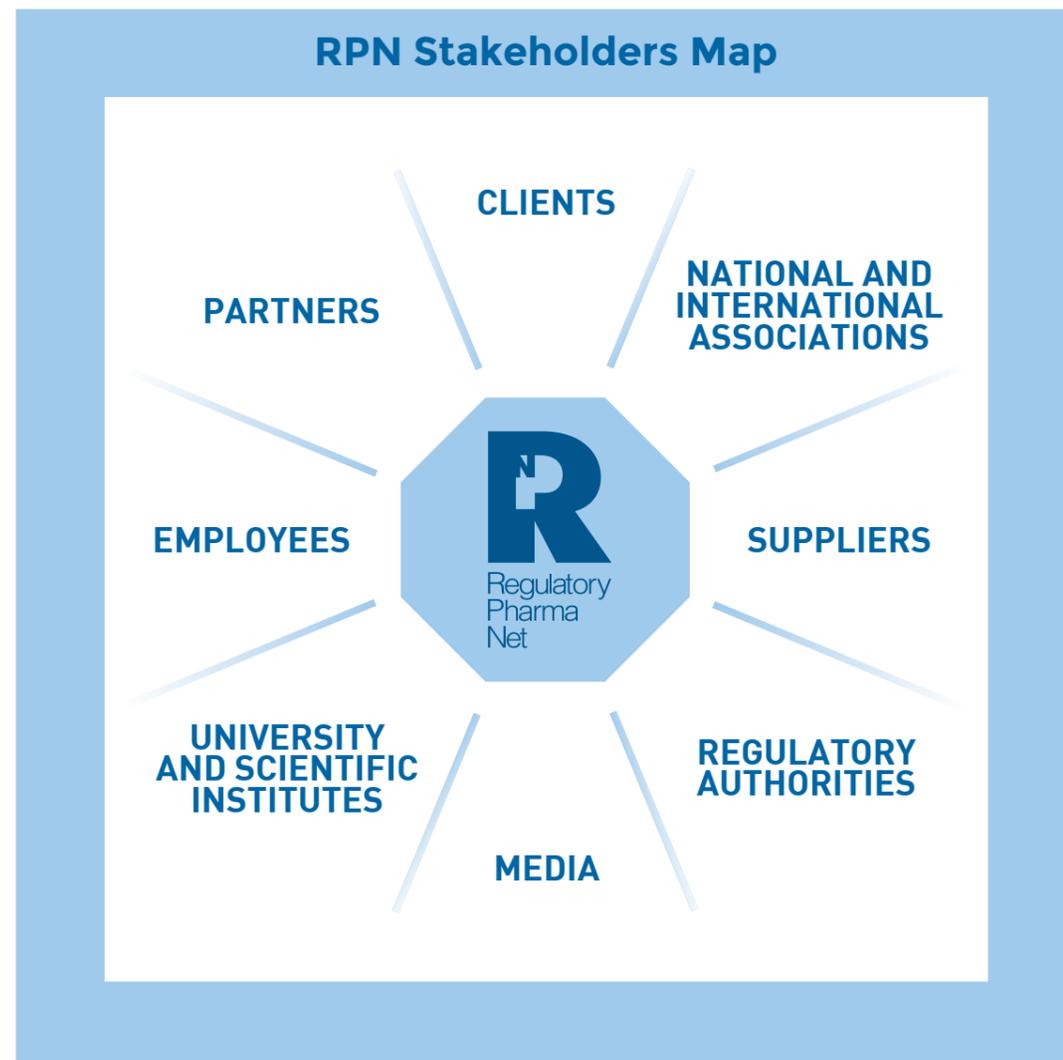
#### 2. Stakeholders Engagement and Relevant Themes:

Once the Stakeholders have been mapped according to the four categories previously defined, the real engagement path began, and was carried out through semi-structured

interviews with external (Customers, Partners and Suppliers) and internal (Employees) strategic stakeholders. The result was the identification of the relevant themes for RPN and its stakeholders.

#### 3. RPN Materiality Matrix:

The output of these interviews was rationalised and was used to build the Materiality Matrix reported below. As shown, three themes were given priority both for RPN and its stakeholders, and RPN focused on them in order to define its own strategy.





# 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 periods.

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

- **Financial capital** – The pool of funds that is available to an organisation for use in the production of goods or the provision of services; obtained through financing, such as debt, equity or grants, or generate through operations or investments.
- **Human capital** – People's competencies, capabilities and experience, and their motivations to innovate.
- **Social and Relationship capital** – The institutions and the relationships within and between communities, groups of stakeholders and other networks, and the ability to share information to enhance individual and collective well-being.
- **Natural capital** – All renewable and nonrenewable environmental resources and processes that provide goods or services that support the past, current or future prosperity of an organisation.

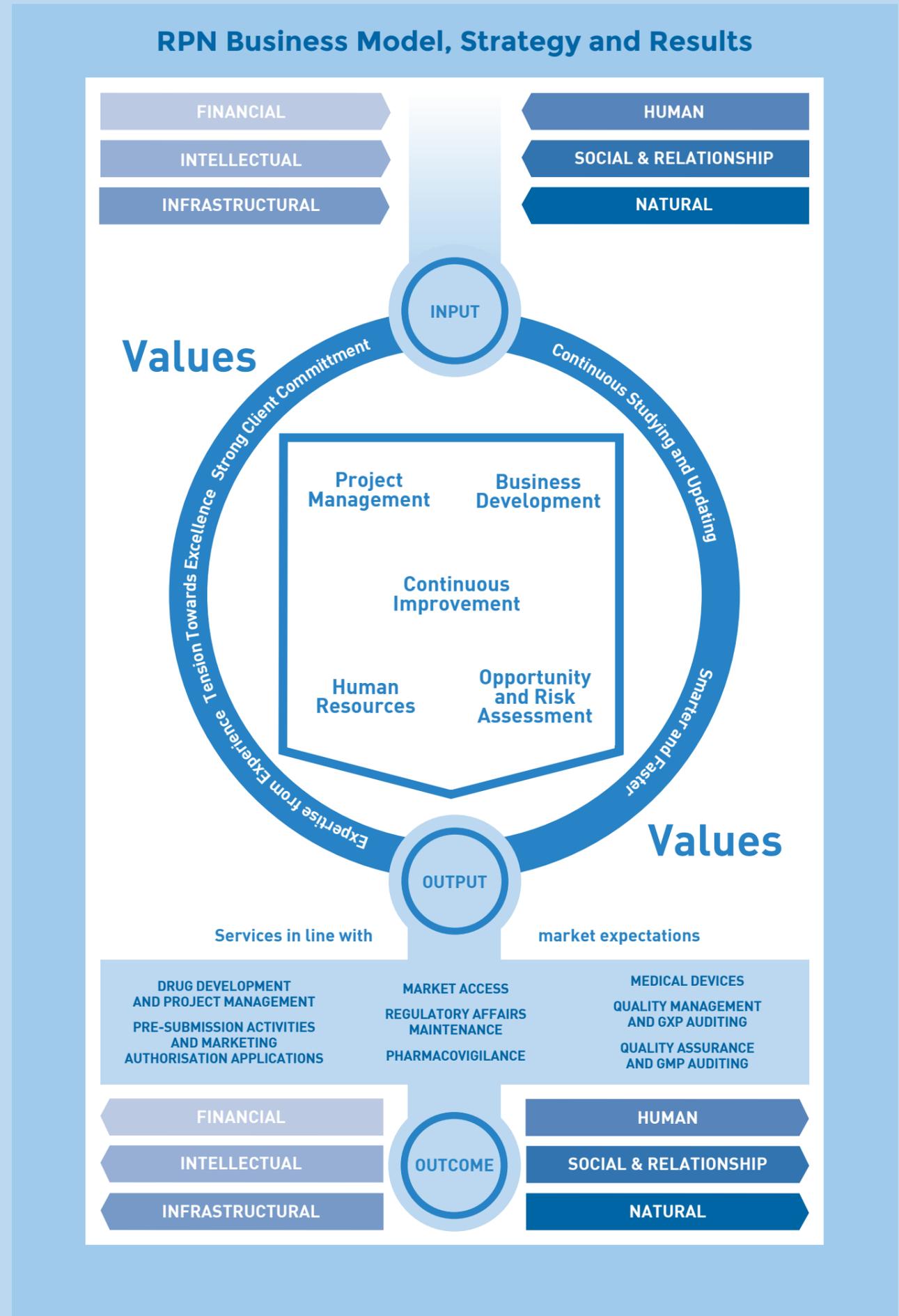
• **Intellectual capital** – Organisational, knowledge-based intangibles "organisational capital" such as tacit knowledge, systems, procedures and protocols.

• **Human capital** – People's competencies, capabilities and experience, and their motivations to innovate.

• **Social and Relationship capital** – The institutions and the relationships within and between communities, groups of stakeholders and other networks, and the ability to share information to enhance individual and collective well-being.

• **Natural capital** – All renewable and nonrenewable environmental resources and processes that provide goods or services that support the past, current or future prosperity of an organisation.

In order to face up and win the market challenges, RPN has structured its business model as follows.



### RPN Strategy

2017 was a very disruptive year for RPN: the combined results of risk assessment and stakeholders' engagement have guided RPN in defining its long term strategy based on three pillars:

- International and National Growth
- Empowering People
- Organisational Development

The three strategic pillars represented for RPN the starting point for the development of the Balanced Scorecard, an international well known methodology, useful for translating the company's strategy into action. In this way, an Integrated Strategic Map is obtained, perfectly in line with Integrated Thinking at the base of the Integrated Report.

#### • Performance on Capitals Dimension

The expected performance on the six different Capitals;

#### • Stakeholders Dimension

The proposed value to be generated for all key stakeholders and not only for the Client and Market;

#### • Projects, Processes, and Organisation

The organisational dimension, and the related processes, remains the pivot around which the strategic thinking rotates;

#### • Available Capitals Dimension

The base of the functioning of the Strategic Map will always be the available capital such as people, technological and information resources, knowledge, organisational heritage and the climate of action.

Once the Strategic Map has been defined and shared, a series of objectives have been assigned to the various managers (measured through Key Performance Indicators) whose

results have been monitored throughout the year representing the Company overall ability to create integrated value. Below the most strategic objectives carried on through 2017:

### International and National Growth

- Turnover increase
- Improvement of Customers' Project Engagement
- Brand Identity and Market Positioning improvement
- Networking development and qualification; External Relations Reinforcement
- Customer Portfolio expansion
- Service diversification

### Empowering People

- Strengthening of internal communication and Know-how capitalisation
- Enhancement of people's technical and soft skills

### Organisational Development

- Improvement of Project's economic control
- High level of innovation in ICT services
- Adoption of Enterprise social network platforms
- Improvement of external communication tools
- New Organisational Model implementation and updating ISO Certification to 2015 standard

### RPN Strategic Map Model



## PERFORMANCE 2017

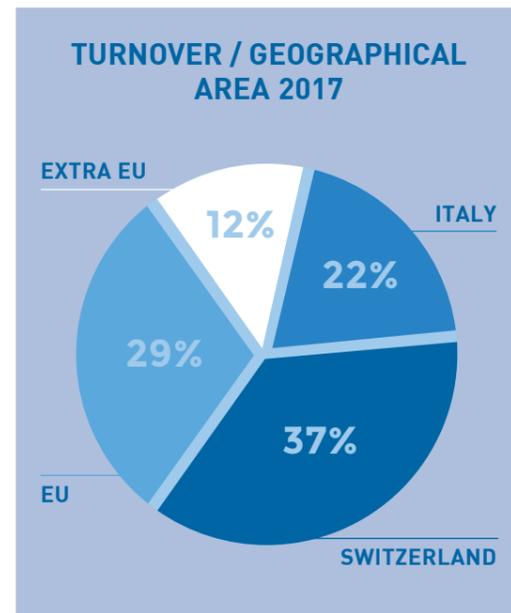
In this chapter are reported the main results obtained by RPN during 2017 on each capital.

### FINANCIAL CAPITAL

#### Highlights

- Turnover: more than 3,000,000 € (+7%)
- Equity: 100%
- Value added distributed to stakeholders: more than 2,500,000 €

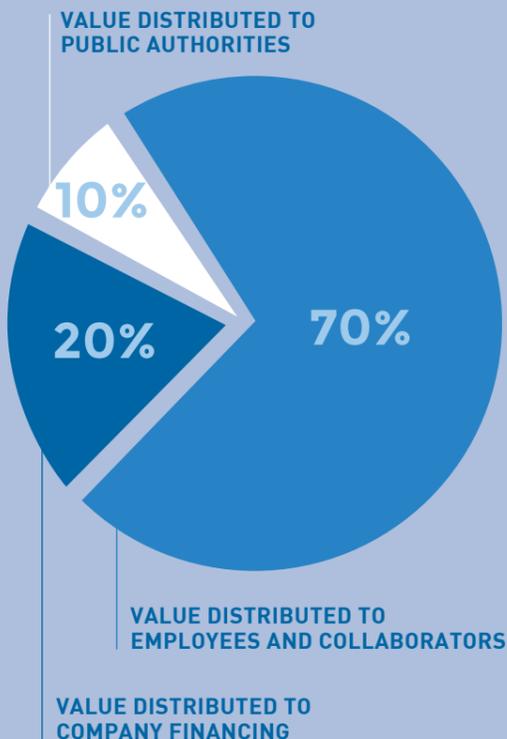
Throughout 2017, more than 40% of the turnover was relevant to the management of International projects. More specifically, the geographical distribution of the 2017 turnover is represented in the graphs reported below



### ADDED VALUE DISTRIBUTION IN RPN

*Added Value measures the capacity of any company in generating additional resources to be allocated among some main categories of stakeholders.*

*In 2017, RPN distributed among its stakeholders more than 2,5 million Euro. The main recipients of this value were the employees, who received more than 70%, while 20% of the total of value added went to the Company for self-financing and the portion paid to the Public Administration in the form of taxes and fees was around 10% of the distributed value.*



### INTELLECTUAL CAPITAL

#### 2017: RPN faces up a Business Process Re-engineering (BPR) project

To face the challenges with ever greater force in 2017 RPN has identified 3 processes whose re-engineering was a priority in order to support the strong growth of the organisation:

1. Project Management
2. Business Development
3. HR Management

According to the BPR method, each process as been re-engineered by a specific working group, aimed at improving the alignment with the Corporate strategy, enhancing the process' performances and clearly defining roles and responsibilities.

#### RPN updates to Quality Management System ISO 9001: 2015

*ISO 9001 is an International standard that sets out the requirements for a Quality Management System. It helps businesses and organisations to be more effective and to improve customer satisfaction. The last version of the standard ISO 9001:2015 now is focused on the Risk based Thinking on the leadership widespread at every organisation level, and on the well-known continuous improvement approach.*

**RPN updated to the Quality Management System Certification ISO 9001: 2015 on March 2018**

## INFRASTRUCTURAL CAPITAL

In 2017, as said, the reengineering project of the three strategic processes carried out in RPN led, as a natural consequence, the upgrade of the supporting ERP technology from a management perspective and in particular for the phases of planning and monitoring the projects' progresses.

### Work in progress

#### RPN goes digital

Use of Office 365 tools, such as SharePoint, OneDrive, Outlook and Teams (with focus on Corporate Social Networking) to enhance teamwork and, more generally, Corporate internal communication.

#### A new office to enhance Smart Working

In 2017, RPN conducted a cost / benefit assessment on its logistical assets in order to identify the most coherent solutions with the business evolution and its internal needs. At the end of the year, the purchase of the new office, 500 square meters in the Pisa city center, was completed. The layout of the new office will be co-designed together with the Organisation's stakeholders (especially employees) in order to maximise the well-being at work and the eco-orientation of the Company.

## HUMAN CAPITAL

### Highlights

- **30** Employees and collaborators
- **Average training hours per employee: more than 70**

In RPN, people and culture really matter. Infact, people are connected, guided and inspired by RPN cultural characteristics and values.

RPN always works at ensuring its people's commitment to a business that acts quickly, empowers them and offers a range of development opportunities.

During 2017, RPN has empowered its employee's competences by training all of them and structuring a training path to guarantee a high competence level in the entire organisation.

### Work in progress

#### A structured incentive system

It has just been launched (April 2018) for all the employees to guarantee them a higher level of wellbeing at work. The bonus is determined by a balanced mix of soft skills together with both strategic and individual goals.

#### Academy

RPN Academy is based on three pillars:

- Continuous technical updating for Seniors
- Technical training for Juniors
- Management and soft skills

## SOCIAL AND RELATIONSHIP CAPITAL

### Highlights

- **Clients: 99**
- **70 %** customer loyalty rate

The stakeholder engagement path conducted by RPN in 2017 allowed the Organisation to strength its relationship with its customers and to better understand the way in which its stakeholders, in particular clients, see and describe RPN, as reported below.

### RPN means

- A-level service
- Flexibility
- Best performer
- Competence
- Made up of people and not of processes
- Client-oriented
- High quality way of working
- Scientific approach
- Professional approach
- Objective-oriented
- Trust
- Scientific background

In 2017, RPN decided to expand its client's portfolio by implementing new external communication strategies to search and involve new clients.

The result has exceeded the expectations, with 29 new clients in 2017:

	2016	2017
Already clients in the previous year/s	66	70
New clients	19	29
Total active clients	85	99

## NATURAL CAPITAL

### Highlights

- **Energy consumption**  
Per-capita electricity consumption: **359 Kw**  
Per-capita gas consumption: **99 Scm**
- **Resources consumption**  
Per-capita paper consumption: **22 kg**

### Work in progress

RPN is committed to develop a culture of paper use reduction, that will be carried out thanks to a strong effort towards digital transformation. For 2018, RPN set the ambitious target of reducing its paper consumption by 10%.

# E

## OUTLOOK

In 2017, RPN embarked on a path of Organisational Development, started with a Strategic Visioning activity, which saw the involvement of its main internal and external stakeholders.

This led to the definition of RPN strategic objectives in the Balanced ScoreCard.

Throughout 2018 RPN will continue this path of transformation and growth.

RPN strategy aims to grow in terms of revenues from both new and existing customers, and to increase its market share. This will be possible thanks to a continuous and greater effort to understand the dynamics of the market in which the Company competes and the context in which it operates daily.

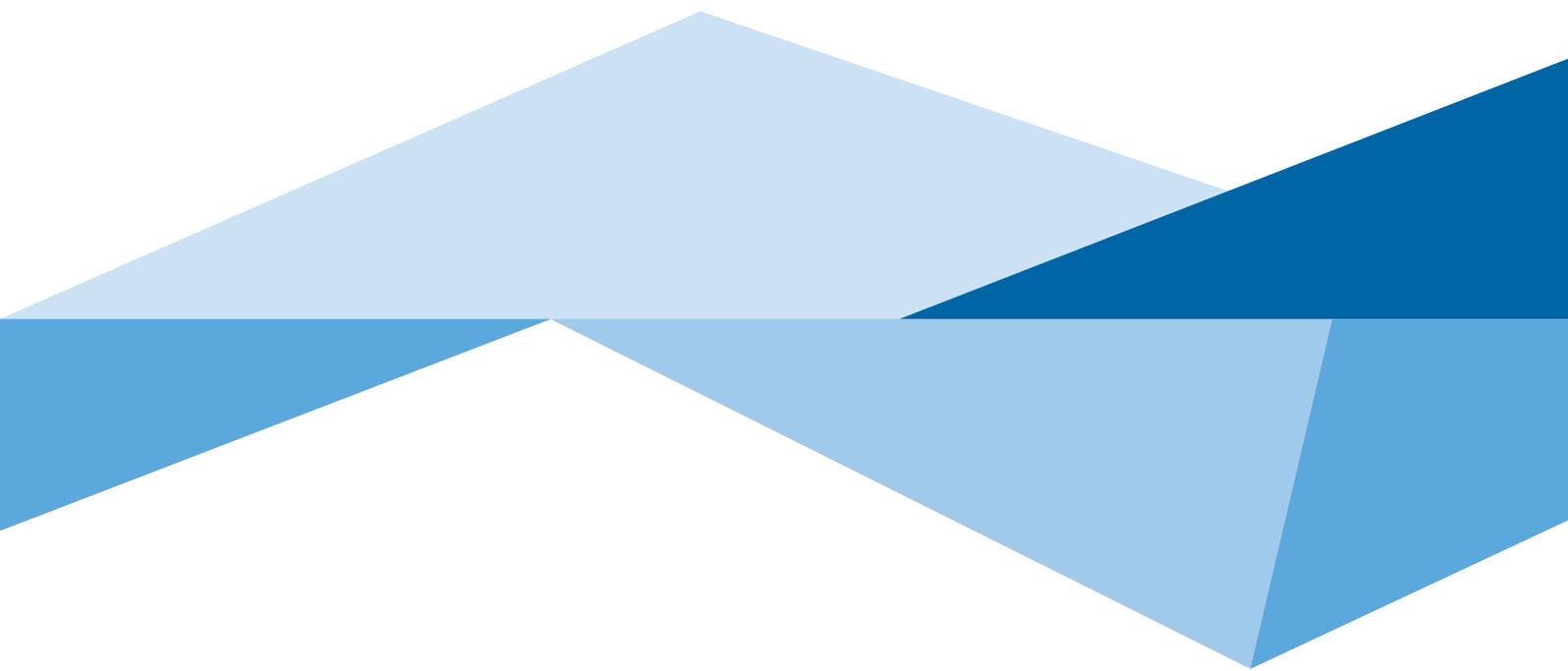
RPN will grow also spatially: in 2018 it will move to a bigger office, where communication and collaboration will be facilitated by the new design. Both individual and team growth will continue throughout 2018: RPN people will be able to enrich their skills and motivation, and teams will be characterised by the empowerment of Company's culture and values.

The new location will represent the ideal office where RPN will continue the path taken last year by strengthening the digital transformation with a particular focus on management control, thanks to the introduction of new digital tools. RPN will proceed focusing on the standardisation, capitalisation and sharing of its know-how, facing the new challenges of the future.

In collaboration with



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Regulatory  
Pharma  
Net

Corso Italia, 108  
56125 Pisa Italy  
Phone: +39 050 9134  
Fax: +39 050 220 4315  
[www.regulatorypharmanet.com](http://www.regulatorypharmanet.com)