



Istituto Superiore di Sanità

THREE-YEAR ACTIVITY PLAN **of the Istituto Superiore di Sanità** **2021-2023**

English version

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of the Istituto Superiore di Sanità
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English version

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Three-Year Activity Plan of the Istituto Superiore di Sanità (2021-2023). English version.

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The Three-Year Activity Plan is the strategic and management policy document envisaged for public research institutions by Legislative Decree 218/2016. This plan consists of a presentation of the Istituto Superiore di Sanità (the National Institute of Health in Italy) and its internal organization; it illustrates the reference scenario and presents the summary of the activities performed in 2020, the year of the COVID-19 pandemic. It highlights the general strategies and objectives of the Institute for the 2021-2023 three-year period, with macro-areas of operation and their macro-objectives. Finally, it reports the development of the internal context, including human, instrumental and financial resources.

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Preface

The Three-Year vity Plan (Piano Triennale di Attività, PTA) is a strategic and management document for public research bodies, provided for by Legislative Decree 218/2016 which includes the “Simplification of the Activities of Public Research Bodies”. The plan, as required by the Internal Rules of Procedure of the Istituto Superiore di Sanità (ISS) approved on 2 March 2016, sets the general guidelines for activities, identifies the objectives of the three-year period and determines the financial resources for their achievement and the human resources required.

The year 2019 was a moment of transition for the Institute which was put under the leadership of an external manager following the resignation, in December 2018, of the pro tempore President.

This phase ended with the appointment of a pro tempore President (29 July 2019) who resumed the planning activities. A policy plan was drawn up for the 2019-2023 period which was presented to all the bodies of the ISS, to the social partners and institutional stakeholders, and approved in October 2019.

The activities of 2020 were inevitably affected by the COVID-19 pandemic, which struck our Country heavily in February 2020. The events produced a heavy impact on the life of the ISS which was called upon to play a prominent role in the management of the epidemic it being a Technical-Scientific body and an essential public service as per definition in Note no. 3351 - P 13/03/2020 of the Ministry of Health). The pandemic also slowed down the renewal of the statutory bodies, which were in place only starting from May 2020.

These events required a revision of the plan with an expansion of the timelines of activities.

However, while on the one hand more time was required to formalize the various actions of the program, on the other hand, the administrative and planning activity was constant continuous and consistent with the decisions taken in October 2019. Hence today, with the lessons learned during these months, the Institute is in a position to harmonize its policy guidelines and choices with our Country’s strategic policy for a fresh start.

The 2021-2023 three-year strategy, outlined in accordance with the above-mentioned long-term policy plan (2019-2023), takes into account the extraordinary commitment required to respond to the SARS-CoV-2 pandemic and pursues general objectives aimed at characterizing the ISS as a proactive body capable of responding to the challenges of public health with innovative proposals based on scientific evidence. Through the promotion of scientific research, with initiatives and programs dedicated to the enhancement of its staff and, in particular, of its young researchers, the ISS intends to strengthen its role as leader in public health and as an authoritative and independent point of reference for monitoring, regulatory, evaluation, control, training and information activities in the health domain in Italy, in Europe and in the world.

This document therefore presents the plan of activities developed on the basis of the long-term guidelines approved in 2019, which also inspired the planning documents that have already been approved such as the Performance Plan, the Anti-corruption Plan and the Organizational Plan for Smart Working/Working from Home. In order to foster and promote a comprehensive and integrated vision, each of the documents has been defined consistently and in synergy with the overall picture.

This Plan consists of a main document and an attachment which is an integral part thereof. The first chapter of the main document describes the Institute, its mission, internal organization and human resources. The second chapter provides a brief analysis of the national and international context of the general program and of the action plans of the ISS. The third presents a summary of the activities of 2020, characterized by the health, economic and social emergency associated with the COVID-19 pandemic. The fourth chapter illustrates the strategies and macro-objectives of the Institute, broken down into three-year objectives that define the priorities for the 2021-2023 three-year period. The three-year objectives include activities and actions that come under the categories of Scientific Research, Institutional and Third Mission Activities, provided for by the guidelines for the evaluation of public research bodies, approved by ANVUR in June 2017, within the scope of Legislative Decree 218/2016, in accordance with the policy act of the Minister of Health of 29 December 2017. The fifth and sixth chapters are dedicated to the internal context of the ISS and to the resources required to implement the plan, including the 2021-2023 recruitment plan.

Finally, mention should be made of the extraordinary commitment and ability to adapt of the ISS staff, in all its components, and of their commendable efforts to provide the National Health Service and the Country with all the technical and scientific support during this pandemic which is still under way when this PTA is in the process of being formalized.

The President

Silvio Brusaferrò

1 • Presentation of the Institute and its internal organization

The Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy) is a technical-scientific body of the National Health Service (NHS) and a public research body under oversight by the Ministry of Health (Legislative Decree 218/2016).

In line with its mission, defined in the Statute approved on 24 October 2014, pursuant to Article 2, Legislative Decree 106/2012, the Institute promotes and protects public health through research, control, guidance, regulation, training and information, prevention and surveillance activities, acting in the context of large macro-areas of intervention that cover all the domains of public health.

With almost 2,000 employees (researchers, technical and administrative staff), the ISS is Italy's leading research institute in the biomedical and public health sector and provides support to the Ministry of Health, the Regions, the Autonomous Provinces of Trento and Bolzano and to the entire NHS to inform health policies by collecting scientific evidence, in agreement with the Presidency of the Council of Ministers, the Ministry of Education, the Ministry of University and Research (MUR), the Ministry of Foreign Affairs and International Cooperation (MAECI), the Ministry of the Environment, the Ministry of Transport, and the Ministry of Justice.

The Institute works for the promotion and protection of national and international public health through numerous activities and collaborations with the European Commission, with the main multilateral bodies – CDC (Centers for Disease Control and Prevention), ECDC (European Centre for Disease Prevention and Control), ECHA (European Chemicals Agency), EDQM (European Directorate for the Quality of Medicine and Health care), European Food Security Authority (EFSA), EMA (European Medicines Agency), FAO (Food and Agriculture Organization), IANPHI (International Association of National Public Health Institutes), IARC (International Agency for Research on Cancer), OIE (World Organization of Animal Health), OMCL (Official Medicines Control Laboratory), PHACEE (Public Health Alliance - Central Eastern Europe), UNDP (United Nations Development Program), UNEP (United Nations Environment Program), WB (World Bank), WFP (World Food Program), WHO (World Health Organization) – and with the universities, agencies and institutional technical and scientific counterparts of OECD countries (Organization for Economic Cooperation and Development), with developing and transition countries, with Italian embassies abroad and with foreign embassies in Italy.

The ISS also plays an essential role as source of authoritative and scientifically correct information which it disseminates through its institutional website (www.iss.it), and through a variety of publications, including the *Annali dell'Istituto Superiore di Sanità* (a science journal for public health), available free of charge on the Institute's website. It also communicates through dedicated channels available to the citizens, such as the ISSalute portal, the Museum and telephone helplines.

The institutional site is associated with thematic sites, including: EpiCentro (www.epicentro.iss.it), dedicated to epidemiology for public health; the portal of the National Guidelines System (SNLG; www.iss.it/linee-guida); the portal of the National Centre for Chemical Substances, which includes the Dangerous Preparations Archive (www.cncs.iss.it); the portal of the National Blood Centre (www.centronazionalesangue.it); the Transplant portal

(www.trapianti.gov.it) and the Rare Diseases portal (www.malattierare.gov.it), respectively run by the National Transplant Centre and the National Rare Diseases Centre, in collaboration with the Ministry of Health; the portal of the National Autism Observatory (www.Osservatorionazionaleautismo.it); the portal of the “Heart Project” (www.cuore.iss.it), dedicated to the epidemiology of cardiovascular and cerebrovascular diseases, and to the state of health of the Italian adult population; the “United against AIDS” site, that concerns sexually transmitted infections (www.uniticontrolaids.it), and the site of the national network of Laboratories of National Reference for the measles and rubella MoRoNet (www.moronetlab.it).

And finally, there is also the IRIDA-ARIES infrastructure (<https://irida.iss.it/irida-aries>), a collaborative bioinformatics platform for the collection, analysis and sharing of genomic data on pathogenic microorganisms for the surveillance of infectious diseases.

1.1 • Bodies of the ISS

The President, the Board of Directors, the Scientific Committee, the Statutory Board of Auditors are the bodies that manage the ISS.

According to the Institute’s regulations, the President has the function of coordinating the Institute’s activities and development policies, the Board of Directors has the role of providing administrative and financial guidance, while the Scientific Committee manages and coordinates the scientific activity. These three bodies are responsible for the strategic and planning activities of the Institute, while the Board of Auditors monitors compliance with the provisions of the law, regulations and statutory provisions, and provides for the other tasks entrusted to it by the current legislation, including the monitoring of public spending.

There are additional “Bodies” that operate at the Institute such as: the Independent Assessment Body, which exercises the powers referred to in Article 14 of Legislative Decree no. 150 of 27 October 2009, as amended; the Ethics Committee, which operates as a guiding body that evaluates research and experimentation activities from an ethics standpoint; and the Single Guarantee Committee, appointed by the Director General Decree no. 129 of 29 October 2019, which replaces the Equal Opportunities Committee and the Anti-Mobbing Committee.

1.2 • Internal organization

1.2.1 • Presidency

The Presidency is supported by the following offices:

- President’s Secretariat;
- Scientific Secretariat;
- Scientific Communication Unit;
- Knowledge Unit (Documentation, Library);
- Training Office;
- External Relations office and centre for international affairs;
- Press Office;
- Bioethics Unit.

The support structures operate in synergy, especially for all activities related to communication, press office, and web site.

1.2.2 • Directorate-General

The Directorate-General manages, governs and organizes all resources.

The Directorate-General comprises two directorates: the Institutional and Legal Affairs Office and the Logistics, Projects and Maintenance Office.

There are also the following support structures:

- Director General's Secretariat;
- Occupational Health and Safety;
- Management Planning and Control;
- Information Technology;
- Support to the Responsibilities for purchasing procedures;
- Security and Access Control.

1.2.3 • Technical-scientific operational area

The technical-scientific operational area is organized into 6 Departments, 14 National Centres, 2 Reference Centres, 5 Technical-Scientific Services. The Departments and Centres are organized into Units (Box 1).

Other Units operating at the Institute include:

- the *Notified Body* (ON373), which carries out conformity assessments of medical devices and of *in vitro* medical and diagnostic devices, also through inspections, for the purpose of issuing the EC certifications required by the European legislation in force for specific sectors;
- the *National Transplant Centre* (NTC), established by Law no. 91 of April 1999, which is the Technical-Scientific body responsible for coordinating the National Transplant Network. The NTC manages, coordinates, regulates and supervises the transplant network for organs, tissues, and cells and also organizes training activities. Through coordination with the Regional Centres of Reference, the NTC also carries out organizational and health-related activities for the network. Within its framework there is a structure, called Operational NTC, in 24x7 service, with the operational function of allocating organs to national transplant programs and, in particular, it runs the emergency program, the paediatric program, the hyper-immune program, the split-liver program, the cross-over program for kidneys, exchange of organs with foreign countries, refunds and surpluses.
- the *National Blood Centre* (NBC) which was established by Decree of the Minister of Health of 26 April 2007, with the function of coordinating and controlling the technical and scientific aspects of the national transfusion system with regard to the matters governed by Law 219/2005 and by the decrees transposing European directives. The NBC is a national coordination body.

Box 1. Departments, Centres and Technical-Scientific Services of the ISS

Departments

Cardiovascular, endocrine-metabolic diseases and aging
Environment and health
Food safety, nutrition and veterinary public health
Infectious diseases
National centre for addictions and doping
Neurosciences
Oncology and molecular medicine

Centres

National Centre for Addiction and doping
National Centre for Animal research and welfare
National Centre for Chemicals, cosmetics and consumer protection
National Centre for Clinical excellence, healthcare quality and safety
National Centre for Control and assessment of medicines
National Centre for Disease prevention and health promotion
National Centre for Drug research and evaluation
National Centre for Global health
National Centre for Health technology assessment
National Centre for HIV/AIDS research
National Centre for Innovative technologies in public health
National Centre for Radiation protection and computational physics
National Centre for Rare diseases
National Centre for Telemedicine and new healthcare technologies
Reference Centre for Gender Medicine
Reference Centre for Behavioural Sciences and Mental Health

Technical-Scientific Services

Biological Service
Grant office and Technological Transfer
Core Facilities
Research Coordination and Support
Statistics

1.2.4 • Administrative operational area

The administrative operational area is divided into two structures of executive management level: the Central Directorate of General Affairs and the Central Directorate of Human and Economic Resources. The two structures are organized into separate administrative offices (Box 2).

Box 2. Administrative breakdown of the management structures of the ISS

Central Directorate for General Affairs

- Office of General Affairs
- Office for employment disputes resolution and disciplinary measures. Application of anti-corruption and transparency laws.

Central Directorate for Human and Economic Resources

- Office of budget, accounts and tax affairs, Economic Treatment of personnel
- Office for terms and conditions of employment regulations of permanent and fixed-term staff and trade union relations
- Office for recruitment, scholarships and training
- Contracts Office
- Project and convention office

2 • Background

In line with its mission of “promoting and protecting national and international public health through research, control, guidance, regulation and training”, the ISS produces scientific knowledge from basic and applied experimental research, it monitors and manages the surveillance of health-related phenomena, and on the basis of these activities, it provides technical and scientific advice to the various institutions and operates in some contexts as a regulator. In addition, the ISS disseminates knowledge and scientific evidence, making it available to decision makers, operators and citizens, and it takes action in macro-areas covering almost all domains of public health.

The main documents of reference underpinning the ISS policy activities are: at national level, the National Research Plan, the National Health Research Plan, the Guidance Act of the Ministry of Health and the specific plans approved over the years (National Prevention Plan, National Chronic Disease Plan, Mental Health Action Plan, National Dementia Plan, National Rare Diseases Plan, National Vaccine Prevention Plan and National Plan for the Prevention of Viral Hepatitis from Viruses B and C); at European and international level, the new Horizon Europe 2021-2027 framework program and the 2030 Agenda of the United Nations General Assembly.

For the future, the implementation of the Institute’s strategic policy will take into account the new context provided by the National Recovery and Resilience Plan (*Piano Nazionale di Ripresa e Resilienza*, PNRR) and by the Europe Next Generation EU – Recovery Plan.

2.1 • National and international context

The 2030 Agenda, adopted by the United Nations General Assembly on 1st January 2016, establishes that sustainable progress and well-being for all require action in the various domains of social and economic development, through an integrated approach. The domain of health is transversal to many of the 17 Sustainable Development Goals (SDGs) of the Agenda that are aimed at eliminating poverty, protecting the planet and ensuring the well-being of the entire population.

The mission of the ISS is consistent with the 2030 Agenda and many of the Institute’s activities are instrumental to the achievement of some of the 17 SDGs, such as:

- *SDG 2* Zero Hunger: putting an end to hunger, achieving food safety, improving nutrition, promoting sustainable agriculture
- *SDG 3* Good Health and Wellbeing: ensure good health and wellbeing for all and for people of all ages.
- *SDG 4* Quality Education: provide quality, equitable and inclusive education, and life-long learning opportunities for all.
- *SDG 5* Gender Equality: achieve gender equality and empowerment (greater strength, self-esteem and awareness) for all women and girls.
- *SDG 6* Clean Water and Sanitation: access to water and sanitation for all and sustainable management of water and sanitatiton facilities.
- *SDG 10* Reduced Inequalities: reduce disparities between and within countries.
- *SDG 13* Climate Action: combat climate change: promote actions at all levels to fight climate change.

In the strategic plan of Horizon Europe – the European Union (EU) 2021-2027 framework program aimed at generating knowledge, at strengthening the impact of research and innovation in the development, support and implementation of EU policies – Health represents the first of the 6 clusters of Pillar II “Global Challenges and European Industrial Competitiveness”.

Horizon Europe analyses the problems that research on health issues and society are facing now and in the near future and identifies six global, complex and interdependent challenges:

- staying healthy in a rapidly changing society;
- living and working in a health-promoting environment;
- tackling diseases and reducing disease burden;
- ensuring access to innovative, sustainable and high-quality health care in the EU;
- unlocking the full potential of new tools, technologies and digital solutions for a society that seeks to constantly improve the protection of public health;
- maintaining an innovative, sustainable and globally competitive health industry.

Diseases and disabilities constitute a severe socio-economic burden for citizens and health systems in the EU and around the world. Today, the COVID-19 pandemic makes it clear that infectious diseases represent a serious risk to people’s mental and physical health and a serious threat to global health security; it should not be forgotten that, alongside the current epidemic, there are also global challenges such as, for example, chronic degenerative diseases, infections resistant to antimicrobials, mental disorders and rare diseases.

These challenges require greater health promotion, better disease prevention and more effective solutions to manage diseases and reduce the burden of disease. At the same time, they need more accessible, sustainable and efficient health care systems to promote and protect the health of all and to provide high quality health care to all citizens. Research and innovation activities are instrumental in providing new knowledge and skills, in improving our understanding of health and diseases, and in developing innovative methodological and technological solutions.

Despite the specific features of the Italian framework, the priorities and challenges identified by the above-mentioned international documents apply fully to our country.

The recently published 2021-2027 National Research Plan (*Piano Nazionale della Ricerca*, PNR) identifies “Health” as one of the six major areas of research and innovation, pointing out that the state of health in the Country is threatened by a number of factors: the progressive aging of the population; the increase in behavioural risk factors (smoking, alcohol abuse, unhealthy diet, sedentary lifestyle, vaccination hesitation) and non-behavioural risk factors (pollution, environment, climate, urbanization, antibiotic resistance, digital delay and digital divide); and the increase in chronic-degenerative diseases and rare diseases affecting the cardio-vascular, renal, respiratory and digestive systems, the central nervous system and metabolism.

These issues are also present in the National Health Research Plan (*Piano Nazionale della Ricerca Sanitaria*, PNRS), addressed to all researchers working within the NHS and aimed – in addition to the production of scientific knowledge – at the improvement of care, treatment and services, with the ultimate aim of significantly increasing the health of citizens and therefore their life expectation and their quality of life.

The policy document of the Ministry of Health for the year 2021 recognizes health promotion as a determining prerequisite for well-being, quality of life but also for the sustainability of the health system. European healthcare systems face major challenges, such as aging, co-morbidities, shortage of health workers and the growing problem of preventable non-communicable diseases,

including neurodegenerative diseases, mental disorders and rare diseases. It recognizes that it is essential to adopt a One Health vision for the future, an integral part of the Global Health paradigm, which looks at the close connections between human, animal and environmental health. In this context, the first real challenge is to improve the sustainability of the national health service by redirecting health expenditure and promoting new fund-raising strategies and methods, also in community and international settings. Health research will produce innovative clinical applications, which will offer patients new and more effective treatments and care plans.

The new National Prevention Plan (*Piano Nazionale della Prevenzione*, PNP, launched for the 2020-2025 five-year period, represents a fundamental tool for the implementation of the Essential Levels of Care (*Livelli Essenziali di Assistenza*, LEA) “Collective prevention and public health”, divided into six macro-objectives: non-communicable chronic diseases, addictions and related problems, road and domestic accidents, injuries and accidents in the workplace, occupational diseases, environment, climate and health, and priority infectious diseases. From this standpoint, the PNP follows the directions contained in the specific plans in force, such as the National Chronicity Plan, the Mental Health Action Plan and the National Vaccine Prevention Plan.

The COVID-19 pandemic has demonstrated the need for coordinated global action. While on the one hand, the pandemic has called attention to the criticalities of health systems, the disparities in social protection and the structural inequalities within the same country and between countries, on the other hand, a strong need for coherence and synergy between national systems has emerged, considering that these systems are strongly interconnected, especially when faced with the need to respond to a global health crisis. As highlighted by the European Commission, COVID-19 is unlikely to be the only global or pan-European crisis of our century. The new European Health Emergency Preparedness and Response Authority (HERA), proposed by the Commission, aims to strengthen the EU’s capacity to respond to new, emerging cross-border threats to human health, setting priorities and identifying opportunities for the coming years. The One Health approach, an integral part of the Global Health paradigm, which looks at the close connections between human, animal and environmental health, and is recommended by the most important international organizations (WHO, FAO, OIE), is fully implemented in the ISS structures and in the integration of their competencies.

The pandemic, which has rapidly spread throughout Europe starting from the early months of 2020, has further worsened the state of health in our Country and in the world. The virus has struck individuals and communities directly by increasing morbidity and mortality, but also, indirectly, by overloading the healthcare systems and by imposing the need for physical distancing that has had a negative impact on both social and psychological well-being and on the economy in general.

As happens in the case of extraordinary events such as those linked to pandemics, the reaction of our Country and of other Countries across the world was twofold: an immediate response, which is still under way, and a medium/long-term response. In our Country the long-term response has taken the form of the Recovery and Resilience Plan, which identifies the basic pillars for healthcare response (e.g., public health and preparedness, environment and climate, primary care and proximity, information systems, biomedical research, etc.) that commands the commitment of the ISS for years to come.

This unprecedented emergency period, which has seen the ISS involved from the outset with its multiple functions, has required and will continue to require adaptations and innovations

in the Institute's activities and strategies, consistently with its statutory mandate and with the long-term policies approved by the Institute's Board of Directors on 1st October 2019.

3 • Activities of the Institute in 2020, the year of the COVID-19 pandemic

3.1 • ISS and the COVID-19 pandemic

The year 2020 was characterized by the COVID-19 pandemic, an emergency that is still under way and that has put Countries and institutions to the test. The pandemic has also strongly affected the activities of the ISS, but at the same time it has been an opportunity for developing skills and knowledge. The effort to support the Country in facing an event of unprecedented proportions did not prevent the activities that had been previously planned, but only slowed them down; indeed, the policy actions have been uninterruptedly pursued and many of the objectives have been achieved.

In providing the Country with an essential service, the ISS was involved in its dual role of research institution and Technical-Scientific body of the NHS. All the branches of the ISS (Departments, National Centres and Reference Centres, Services and other structures) contributed to the effort by:

- immediately ensuring an integrated epidemiological and microbiological surveillance, jointly with the Regions and Autonomous Provinces (Ordinance of the Head of the Civil Protection Department no. 460 of 27/02/2020);
- being recognised the status of an essential public service (Note of the Ministry of Health no. 3351 - P 13/03/2020);
- participating with its experts in the various technical task forces, both international (WHO, ECDC) and national (Crisis Unit, Task Force, etc.), providing technical and scientific support to 'preparedness' actions and response actions to COVID-19, in compliance with the regulatory and operational indications provided by the Technical-Scientific Committee (CTS) of the Civil Protection and by the various Ministries, and subsequently by developing measures to mitigate and contain the pandemic;
- actively participating in the CTS (over 130 meetings whose minutes are available) and in the Control Room, set up by the Government to monitor the evolution of the pandemic and to support the public health actions to be implemented for controlling the pandemic at national and regional level and in numerous sectors of society such as, in particular, schools, transport, sports activities, catering, bathing, tourist activities in winter resorts, large events, trade fairs, shows, tourism and industry;
- activating 22 Working Groups on specific topics related to the pandemic, bringing in external experts who worked jointly with the internal experts of the ISS and who summarized in guidance reports all the most up-to-date scientific evidence on the matter, also with a view to providing accurate and timely answers to the doubts expressed by the scientific community and the institutional and social stakeholders;
- ensuring, through the Medical Devices Working Group, which made use of the Notified Body's expertise for most of the validation activities in derogation of the surgical masks as required by Article 15 (2) of Decree-Law no. 18 of 17 March 2020, converted with amendments into Law no. 27 and amended by Law no. 77;

- establishing the Technical Committee provided for by Article 66-bis of Law no. 77, chaired by an ISS expert, who defined the simplified criteria for the validation in derogation of imported surgical masks, an activity that the aforementioned Law entrusted to the Regions while attributing the task of monitoring to the ISS;
- providing, with regard to surgical masks, the competent authorities, the NAS and the Guardia di Finanza units, with continuous support in controlling the market;
- ensuring continuous support for training dedicated to NHS staff and other sectors (e.g. the schools) through Distance Learning;
- continuing to carry out training activities and dissemination of information to counteract fake news, through communication channels addressed to the general population;
- carrying out online activities (webinars) for updating information, sharing experiences and best practices on rare diseases within the national and international community;
- contributing to the preparation of the COVID-19 vaccination campaign;
- maintaining and expanding its network of international collaborations, both in the institutional sphere and in the area of scientific research.

3.1.1 • Integrated surveillance

Even before the outbreak of COVID-19 in Italy, through EpiCentro, the internal portal dedicated to epidemiology for public health, the Institute had begun to disseminate information about the epidemic in China, the biological characteristics of the virus, the passage from animal host to man and transmissibility. The first two cases of COVID-19 imported into Italy and the first local case were confirmed by the ISS on 21 February 2020.

Starting from February 28, the ISS coordinated the integrated epidemiological and microbiological surveillance system which remained in operation until 10 April 2020, when the task of confirming tests was handed over to the Regions / Autonomous Provinces (PA); to cope with the workload in that early period of the pandemic, the institute's laboratories had to operate day and night seven days a week to confirm the tests of suspected cases.

The surveillance activity, documented the spread of the COVID-19 epidemic over time and space; on the EpiCentro portal from 10 March to 31 December 2020 the following reports were published:

- 46 periodic national updates to the epidemiological "COVID-19 Epidemic" Report, each update containing appendices with regional details;
- 35 infographics and test results of patients who died in relation to COVID-19 and in-depth reports on various topics, including: updates on interventional studies and vaccines, SARS-CoV-2 infection in pregnancy and in the puerperium, perinatal health, contrasting fake news, vulnerable populations, as well as information materials for the population on healthy lifestyles during the pandemic;
- from 8 May to the present day (15/02/21), following the entry into force of the Decree of 30 April 2020 of the Ministry of Health, the ISS has produced 39 weekly reports titled "Monitoring COVID-19", containing a risk analysis of the epidemic at the regional level,

which is the result of on-going dialogue and exchanges with the Regions and Autonomous Provinces and with the Ministry of Health.

3.1.2 • Working Groups and "ISS COVID Reports"

At the time of greatest impact of the COVID-19 emergency in the Country, 22 working groups (WG) were set up (Table 1), coordinated by the Scientific Secretariat of the Presidency and composed of 332 ISS experts in collaboration with 114 external experts from public institutions (ISTAT, *Istituto Nazionale di Statistica*, National Institute of Statistics; INAIL, *Istituto Nazionale Assicurazione Infortuni sul Lavoro*, National Institute on Insurance against Accidents in the Workplace), Health Institutions (Ministry of Health), Ministries, National Federation of the Associations of Surgeons and Dentists (FNOMCEO), Universities, and Non-university research bodies (Scientific Societies, Foundations, Services).

Table 1. Name of the COVID-19 Working Groups

WG	Name
1	Technologies in Support of the Fight against COVID-19
2	Infection Prevention and Control
3	Training Health
4	Communication
5	Drugs and Clinical Trials
6	Medical Devices
7	Causes of death
8	Immunology
9	Microbiology Diagnostics and Surveillance: Molecular Analysis Aspects and Serology
10	Veterinary Medicine and Food Safety
11	Environment – Waste
12	Preparedness
13	Diagnostic Tests
14	Scientific Updates
15	Biocides and Disinfection Procedures
16	Telemedicine and Digital Health
17	Bioethics
18	Translational Research
19	Rare Diseases
20	Mental Health and Emergencies
21	Epidemiological Data
22	Long-care facilities

The WGs, initially conceived as temporary and transitional structures, actually provided a continuous link between the ISS and the requests coming from the various stakeholders, both institutional (national and territorial) and representatives of the economic and social sectors. In addition, the involvement of many external professionals in the WGs testifies to the role of the ISS as a pole of attraction of skills and knowledge at a time when collaboration between the scientific community and institutional research was imperative.

In 2020, the WGs produced a total of 63 ISS COVID-19 Reports containing guidance, recommendations and procedures, all available in a specific section of the website of the Institute: <https://www.iss.it/rapporti-covid-19>. Many of these reports have also been translated into English.

The reports address a great variety of topics and this reflects the role taken on by the ISS as interlocutor for the issues that emerged as the pandemic continued. By way of example only, during “phase 2”, the ISS provided operational information on the reopening of commercial and tourist activities and on the management of SARS-CoV-2 cases and outbreaks in schools and kindergartens. From 9 April to 27 May 2020, 8 bibliographic newsletters entitled “COVID Contents” were also published, for the scientific updating of health professionals.

3.1.3 • Other actions against the pandemic

In pursuance of Decree-Law no. 9 of 2 March 2020, the ISS examined the masks without the CE mark (Article 34 (3)), carrying out the activities laid down in Article 34 (3) as well as validation activities in derogation (Medical Devices Working Group).

On March 25, the ISS launched a national, prospective, population-based study on SARS-CoV-2 infection in pregnancy, childbirth and puerperium involving all the birth facilities in the Country.

On April 14, the ISS launched an investigation on COVID-19-related deaths in long-term care facilities.

Together with AIFA (*Agenzia Italiana del Farmaco*), the ISS promoted a national study, which was authorized in May, to evaluate the effectiveness of the early administration of plasma obtained from patients recovering from COVID-19.

Together with ISTAT, in 2020 the ISS prepared four reports on the “Impact of the COVID-19 epidemic on the total mortality of the resident population”.

In collaboration with INAIL, joint technical documents have been published on protocols for managing the risk of contagion from SARS-CoV-2 in a wide range of workplaces, from recreational bathing and beach activities, to catering, personal care sector, local public transport in connection with the resumption of commuting (April 2020) and the reopening of schools (December 2020). Technical notes were also produced on laboratory tests for SARS-CoV-2 and their use in public health (ISS, Ministry of Health, Technical-Scientific Committee, Conference of Regions and Autonomous Provinces, National Health Board, FNOMCEO, INMI Lazzaro Spallanzani, WHO) and on the performance of diagnostic tests performed in the offices of General Practitioners and Primary Care Paediatricians (ISS, INAIL, FNOMCEO, Ministry of Health).

With the National Research Council and the European research infrastructure ELIXIR (European Life-science Infrastructure for Biological Information), the ISS contributed to the setting up of the “Italian COVID-19 Data Portal”, (<https://www.covid19dataportal.it/>), a web site connected to the “COVID-19 Data Portal” of the European Commission (<https://www.covid19dataportal.org/>) which was launched in April 2020, to collect and share, in open mode, research data on SARS-CoV-2 and COVID-19.

The ISS Ethics Committee has held many extraordinary meetings to evaluate COVID-19 projects promoted by the Institute and by external structures.

3.1.4 • Training and communication (web site, social media)

With regard to updating information and training, as early as January 29, 2020, the ISS hosted the “State-of-the-Art of COVID-19” scientific meetings on a weekly basis in teleconference, with in-depth analyses and discussions by leading epidemiological and clinical experts.

Through the EDUISS platform, the ISS has provided distance learning courses aimed at all health and socio-health professionals, school support staff and teachers.

A large part of the 2020 training commitment focused on the COVID-19 emergency, with the results shown in Table 2.

Table 2. Distance learning courses on the COVID-19 emergency and the professionals involved in 2020

Title of the course	Dates	Registered participants
Health emergency caused by the new SARS-CoV-2 coronavirus: preparation and contrast	28 February – 28 April	205,515
Prevention and control of infections in the COVID-19 emergency context	30 March – 28 December	200,000
COVID-19 health emergency: management of dialysis patients	21 April – 14 July	2,000
COVID-19 health emergency: information for Contact Tracing (two editions)	28 April – 15 October 2 November 2020 – 21 January 2021	3,681 1,766*
COVID-19 health emergency and gender differences in epidemiology and in clinical work	6 August – 30 October	1,231
COVID-19 health emergency and Psycho-Oncology. Competences to be included in clinical practice	30 April – 14 July	2,000
COVID-19 health emergency: Food risk management	17 July – 21 September	1,624
COVID-19 health emergency: management of dental patients	29 May – 27 November	2,000
Operational guidance for the management of SARS-CoV-2 cases and outbreaks in schools and kindergartens (for health professionals + school staff and teachers)	31 August – 31 December	56,236
COVID-19 vaccination campaign: safe administration of the anti SARS-CoV-2/COVID-19 vaccine	23 December 2020 – 15 April 2021	5,430*
Diagnostic tests carried out in the offices of Primary Care Paediatricians and of General Practitioners	11 December 2020 – 09 March 2021	102*

*as at 31/12/2020

In 2020 there was an almost 20-fold increase in the number of registered users compared to the average of the previous five-year period: 570,000 users against some 30,000. Figure 1, on the other hand, shows the increase in the number of health professionals who completed distance education courses from 2014 to 2020.

The Training Service also held 18 webinars with the Regions, 14 webinars on rare diseases and 6 on long-term healthcare facilities.

In the last months of 2020, in view of the European “Vaccination Day” on 27 December, the ISS was engaged in the creation of a distance education course on the platform of the Institute for operators engaged in the vaccination campaign against SARS-CoV-2. The general objective of the course was to promote the COVID 19 vaccination strategy in the Country, providing the basic skills, tools and technical and scientific contents required to make the campaign a success, including the safe administration of vaccines, and counteracting vaccine hesitancy through the involvement and informed participation of health and social health personnel.

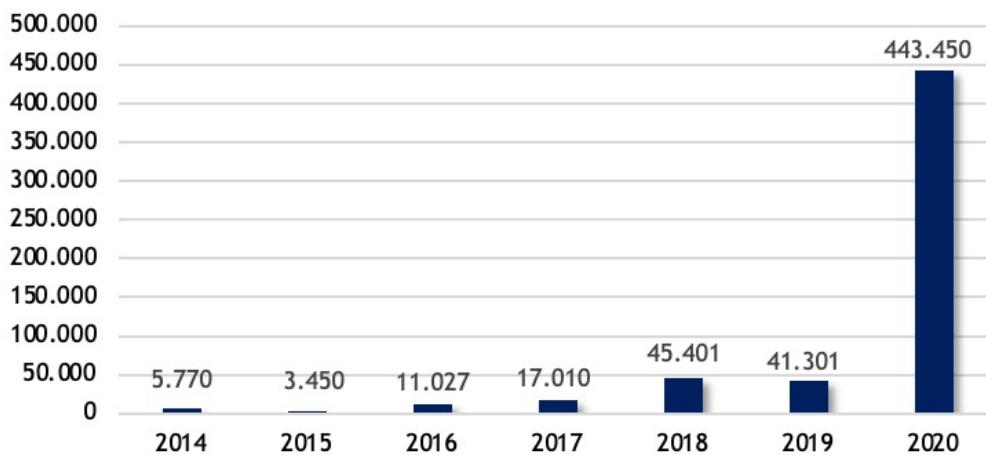


Figure 1. Number of Health professionals who completed the distance education courses run by the ISS (2014-2020)

The relationship with the people in general was constant through the information channels. Since the beginning of the epidemic, fake news was fought and information was provided through editorial activities that included over 100 focuses, more than thirty press releases, fifty FAQs (Frequently Asked Questions) and 9 press conferences. The media coverage of the ISS was considerable, both on traditional media (over 76,000 citations and interviews with the President and Experts) and on social media (over 48,000 followers for the ISS Twitter profile).

Suffice it to consider the “restyling” of the website and the huge number of activities deployed on social media to have an idea of the Institute’s communicative vitality:

- The new corporate website, online from 5 March 2020, has been redesigned to make it more user-friendly. Since that date, more than 5 million new users have been reached, for a total of 17 million pages viewed.
- On Twitter, the followers of the @istsupan increased twelve-fold, going from 5,000 in March to 63,000 in December. On 10 November two accounts were opened: a Facebook account (<https://www.facebook.com/ISS.social>), which had more than 10,500 followers and an Instagram account (https://www.instagram.com/iss_social/), with more than 2,500 followers.

3.2 • Ordinary activities

However, the strong commitment of the ISS on the COVID-19 front did not prevent the Institute from carrying out its ordinary activities, in full compliance with the safety protocols and having recourse to smart working /working from home where appropriate.

One of the new elements in the planning of the Institute starting from 2020 was the grouping of activities of the ISS into macro-areas.

In the 2017-2019 three-year period, the planned activities of the Institute were organized into 16 macro-areas, which involved one or more organizational structures. This model was revised, with a view to greater integration and complementarity of skills, taking into account the challenges and priorities set out in the national and international framework, and according to a vision aimed at eliminating internal “silos” – a direction that was already present in the long-term policy approved in October 2019.

This process, which involved all the heads of the Technical-Scientific structures of the ISS, led to the identification of 7 macro-areas (Figure 2).

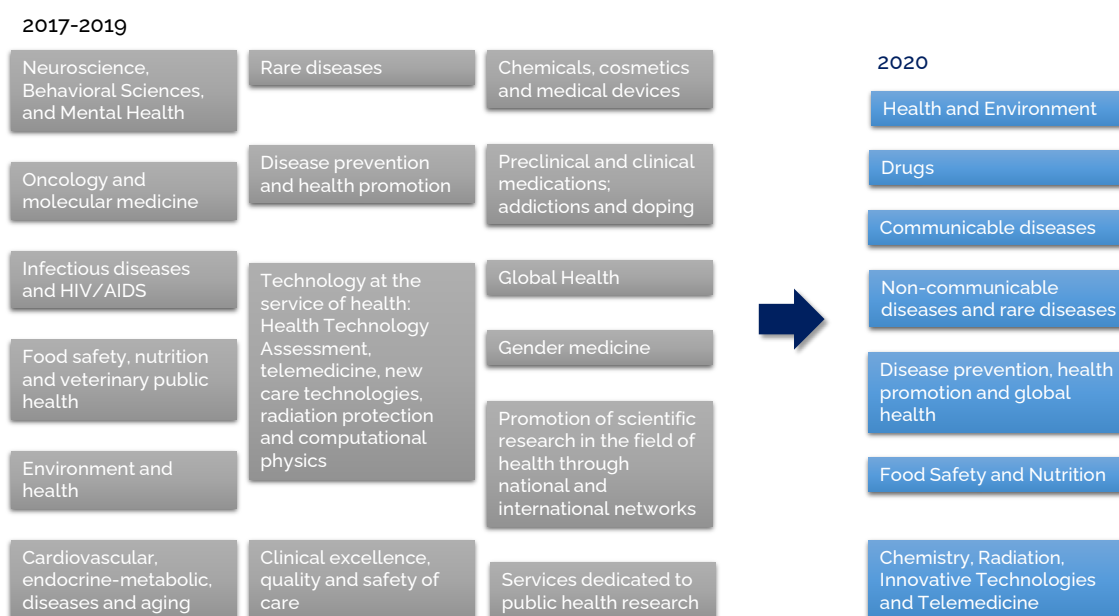


Figure 2. Re-organization of the macro-areas of activity of the ISS

The macro-areas include institutional activities, scientific research and training, information and dissemination activities (third mission), in line with the guidelines for the evaluation of public research bodies, approved by ANVUR (*Agenzia Nazionale di Valutazione del sistema Universitario e della Ricerca*, National Agency for the Evaluation of Universities and Research Bodies) in June 2017, as part of Legislative Decree no. 218 of 25 November 2016, and in accordance with the policy document of the Minister of Health of 29 December 2017.

3.2.1 • Funding and partnership agreements

In 2020, the Institute entered into 167 agreements involving contributions amounting to a total of 37.8 million euros, a figure that is slightly higher than the average of the previous three-year period (36.4 million euros). Among the financing bodies, the Ministry of Health and the European Commission are the most important financiers, representing together 75% of the loans (64% and 11% respectively). Research Bodies, National and International Agencies, Foundations and the Regions contribute about 20% of the funds, while 4% comes from donations associated with COVID-19 and about 1% comes from private funding.

Furthermore, 77 scientific partnership agreements, without funding, were signed with public research bodies, regions, universities, Scientific Institute for Research, Hospitalization and Healthcare (IRCCS), scientific societies, and national and foreign bodies and agencies.

3.2.2 • Research and innovation

The research activities of the ISS have necessarily been reconfigured to comply with the restrictions on the number of workers present in the workplace imposed by the anti-COVID-19 measures. Despite this and in full compliance with the safety protocols, most of the research activities carried out by ISS researchers and technical personnel continued in all the scientific fields with the involvement of all the Institute’s structures. Priority was given to projects with tight deadlines and those involving European and international partnerships.

Of the 167 loans acquired in 2020, 97 were obtained through competitive tenders for a total of € 13.2 million; 9 projects involved research directly related to COVID-19. About 30% of the funding based on competitive tendering came from the European Commission, a slight improvement compared to 2019 (26%). On the other hand, the funds from the Ministry of Health decreased (from 67% to 40%) while funds from other Bodies (Research Bodies, National and International Agencies, Foundations, Regions; “Other” in Figure 3) increased from 7% to 30%.

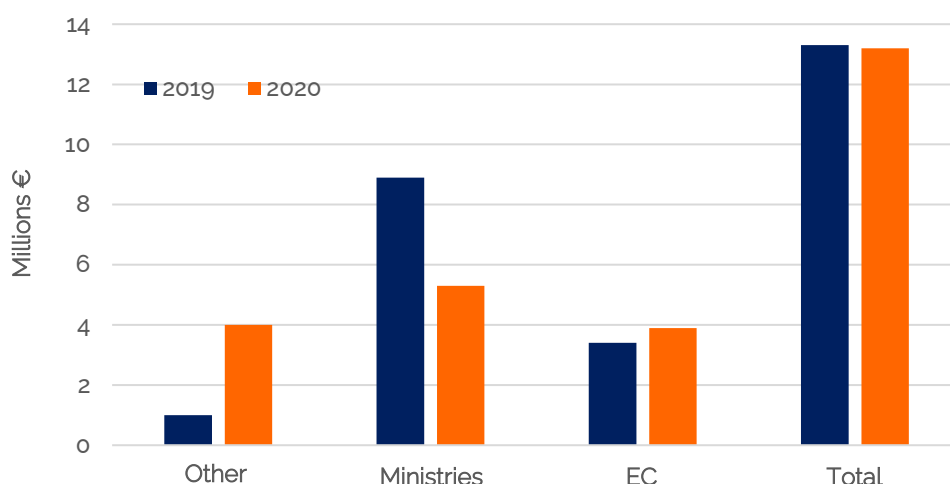


Figure 3. Distribution of funds obtained from competitive tendering in 2019 and 2020

The publications by the ISS experts were over 1,300 in 2020 (recorded in the digital archive of ISS publications, PublISS, which includes, in addition to articles, also monographs and technical reports) (Figure 4). The publications in indexed journals amounted to about 60% of the publications (789 articles and 30 letters or editorials), an increase compared to the average of the previous three years (730 articles). Some 12% of the publications were about issues related to COVID-19.

A more in-depth analysis of scientific production by macro-area and by number of researchers will be available in the coming months, also thanks to the data collected through the Biomedical Research Information System (Research Workflow, [http://ricerca.cbim.it /index.html](http://ricerca.cbim.it/index.html)) of the Ministry of Health.

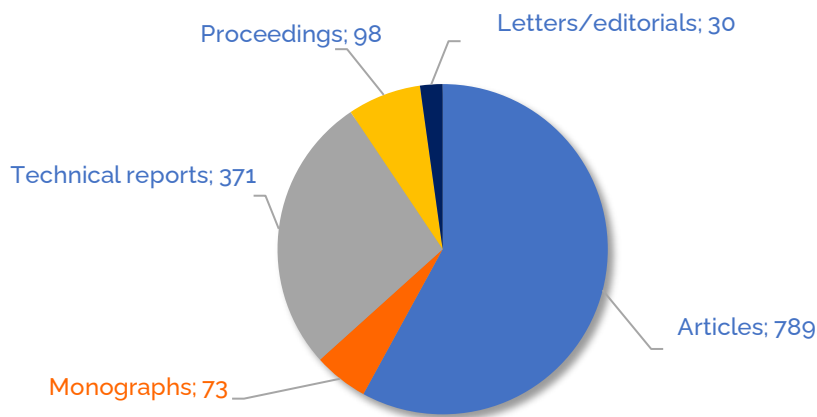


Figure 4. Number and type of publications in 2020

Still in the field of research, 2020 saw the launch of a notice of internal competition funded with the '5 x thousand' contribution to promote the research work of young researchers thanks to which two projects in the field of immunology and HIV-1 infection were funded. At the end of December, the first internal competitive call addressed to ISS researchers was launched at the end of December. The more than 140 projects that were submitted will be evaluated in the early months of 2021, with the help of external, Italian and foreign auditors and of Members of the Scientific Committee of the ISS.

Finally in the course of the year, the ISS made available 56 scholarships for future researchers and put in place 62 PhD agreements in the various sectors of interest that involve several Italian universities. In addition, agreements were signed with the Specialization Schools of 20 Universities. The ISS was included in the training network as a complementary structure in 17 Schools of Specialization in Hygiene and Preventive Medicine and in 27 other Schools that cover all the areas provided for by the system: Medical, Surgical and Clinical Services.

3.2.3 • Other institutional activities

The control, evaluation and regulation activities continued, as well as participation in the various national and international institutional task forces, obviously with the procedures being adapted to the restrictions due to the pandemic emergency.

All Departments/Centres/Services, to a greater or lesser extent, carry out activities involving control, evaluation and the delivery of opinions, sometimes also as a result of the participation of ISS experts in committees, study groups and working groups. Besides its ordinary activities, the Institute has always taken extraordinary action in the presence of health emergencies, at the request of central or regional administrations, for the development of methods of analysis, guidelines and surveillance systems.

Also, the activities associated with Surveillance Systems and with Registers continued; the ISS operates 48 Surveillance Systems and 33 Registers, of these, 34 Surveillance Systems and 22 Registers of national and regional interest are assigned to the Institute by the DPCM of 3 March 2017 being the body of reference for establishing and managing the Surveillance Systems and Registers.

The European Union Reference Laboratory (EURL) and the National Reference Laboratory (NRL) are an additional qualifying element of the Institute: the EURL coordinates, harmonized and provides Technical-Scientific support functions for the network of the NRLs of the Member States while the NRL does the same for the regional laboratories.

Among the activities carried out in the regulatory field, mention can be made of the work done by the secretariat of the Committee on Phase I Clinical Trials, which, besides its usual business which continued regularly, evaluated the trials to be conducted in COVID-19 patients and it offered technical and scientific and regulatory support (including a series of pre-submission hearings with the participation of numerous ISS experts) for the development of new drugs, including vaccines and monoclonal antibodies. During the year, 95 Phase I trials and 445 substantial amendments were evaluated, in line with the previous three-year period (Figure 5 on the left). The Committee and the Technical-Scientific secretariat also assisted AIFA in authorizing the “Non-repetitive uses” (Article 3 (2) of the Ministerial Decree of 16 January 2015), issuing 37 opinions, an unquestionable increase compared to the 2017-2019 three-year period (62 opinions in total).

The ISS also has the task of carrying out technical and scientific assessments in the authorization procedure for projects involving the use of animals (Legislative Decree 26/2014, Article 31), an activity coordinated by the National Centre for Animal Testing and Welfare and involving over 120 ISS experts from 6 Departments, 6 Centres and 2 Services. During 2020, 2000 technical and scientific assessments were performed out of 2142 requests received from 1 January to 31 December 2020 (1451 relating to new projects while 691 were revisions of already authorized projects). From 2014 to date, about 1800 assessments have been made (Figure 5, right).

As described in the previous section, the training activity focused mostly but not entirely on the COVID-19 emergency: 22 non-COVID on-line courses - some of which international – were held in 2020, with a total of almost 75 thousand participants.

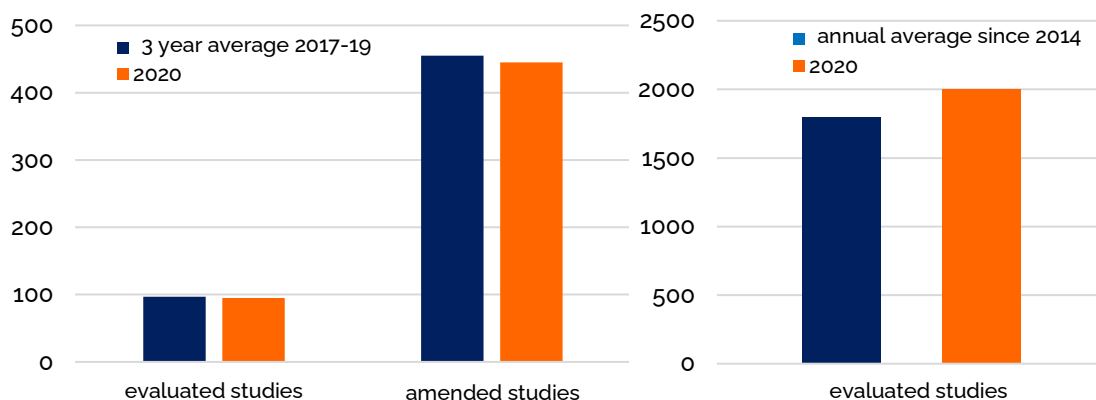


Figure 5. Number of assessments of Phase I trials (left) and for projects entailing the use of animals (right)

The restrictions due to the health emergency instead did limit other important training activities such as those dedicated to schools (Courses on Transversal Skills and Guidance), which were carried out only on-line and involved 3 schools in Rome and its Province on the topic of scientific information against fake news and hoaxes.

As regards international activities, the ISS continued and stepped up its natural dialogue with national government institutions: Ministry of Health, Ministry of Education, Ministry of University and Research, Ministry of Foreign Affairs and International Cooperation, Ministry of the Environment, Ministry of Transport, Ministry of Justice, Presidency of the Council of Ministers.

At EU level, the ISS increased its cooperation with national, European and international networks and links with EU institutions (European Commission, European Parliament, Committee of the Regions, Permanent Representation of Italy to the EU and to the Presidency of the Council of the EU). Through the office in Brussels, the ISS participated in the coordination activities of the European project TO REACH (Transfer of Organisational Innovations for Resilient, Effective, Equitable, Accessible, Sustainable and Comprehensive Health Services and Systems), in the European project Joint Action Health Equity Europe (JAHEE) funded by the European Commission, and directly in the European Joint Program on Rare Diseases (EJP-RD).

In addition, the ISS maintained and developed lines and contacts with the main multilateral organizations: US CDC, ECDC, EFSA, EMA, FAO, IARC, UNDP, WB, WHO and others. Dialogue and exchanges continued with universities, agencies and with the institutional technical and scientific counterparts of OECD Countries, with developing and transition Countries, Italian embassies abroad and foreign embassies in Italy.

The close collaboration with WHO also included the activities of the six Collaborating Centres of WHO: 1) Poliomyelitis, 2) Alcohol and Alcohol-related Problems, 3) Environmental Health in Contaminated Sites, 4) Control of Echinococcosis in Humans and Animals, 5) Radiation and Health, 6) Childhood Obesity; and through the Documentation Centre dedicated to scientific documentation.

As part of the G20, the ISS promoted an initiative aimed at sharing the training activities addressed to the Public Health Officers of member countries, in preparation for the First Health Working Group (26-27 January 2021). In addition, the ISS took part in the activities of the

IANPHI (International Association of National Public Health Institutes) international network, and in the 16th World Congress on Public Health, held on-line from Rome (12-17 October 2020).

In compliance with the policy lines planned in the previous three years, even in the context of the pandemic, the international activity of the ISS continued at full speed using telematic channels and virtual technologies. These activities involved the following areas: Balkans and Caucasus, Eurasia and Asia, Near and Middle East, USA and Canada, Latin America and Africa. Specifically, the *RicercaItaliaAfrica* initiative of the Presidency of the ISS and the organization of the international scientific conference “From 50 years of a malaria-free Italy towards a malaria-free world”, held on-line from the ISS (24 November 2020) .

3.2.4 • Activities for operating the Institute

During the 2020 financial year, the following measures on the new organization of work were adopted, dictated at first by the compelling need to manage the pandemic emergency, and then extended in order to make a better use of the workplace:

- smart-working / working from home, for all the activities that can be effectively carried out remotely at a distance in compliance with the activities map set out in Article 263 of the Decreto Rilancio (Fresh Start Decree);
- stopping all face-to-face activities - conferences, meetings and courses – and replacing them with web platforms for videoconferences;
- possible use of shiftwork in vertical organizational mode;
- reduction in the number of missions, authorized only for undeferrable cases of extreme necessity;
- reorganization of operational functions to reduce internal staff movements, limiting them to the bare minimum.

From the logistical-IT point of view, the ISS initiated the renewal of its systems design and started the expansion of its IT infrastructure (both from a technical and security point of view), it upgraded its technical and administrative structure (management control, privacy, conflict of interest, safety at work) and prepared its technical structure for digital transformation (also in compliance with the indications provided by the Public Function Department (oppure Civil Service Department). Further details on these operations are provided in Chapter 5 which deals with the internal context.

In addition, in October a trial run was made of the “Regulations on the management of conflicts of interest”, available on the institutional website, and two policy documents were drawn up, which will be published soon: “Regulations on the Adoption and Management of Scholarships and PhDs at the ISS”, and the document “Policy for the Management of Research Results (publications and data) produced at the ISS “.

The Single Guarantee Committee for equal opportunities, measures against mobbing and the promotion of well-being met 8 times in 2020. It adopted its own operating rules, prepared a first version of a three-year plan of positive actions, activated its website, interacted with the administration regarding the rules on smart working and gender budgeting, and held an event focusing on the opportunities and new inequalities that may be associated with smart working.

4 • Strategies and general objectives of the Institute

4.1 • Macro-objective 1.

The Institute evolves constantly to meet the present and future public health needs

The Institute actively responds to the challenges of the natural evolution of the NHS by providing scientific evidence and innovative proposals, in accordance with the general three-year objectives, defined on the basis of the national and international framework and within the 7 macro-areas described.

The three-year general objectives include:

- expand scientific knowledge in order to optimize prevention, diagnoses and actions to be taken;
- take actions in support of disease prevention and health promotion;
- conduct research and intervention activities in support of health care organizations and their workers;
- promote and evaluate innovative technologies, eHealth and telemedicine interventions using a multidimensional logic, and adopt Health Technology Assessment (HTA) techniques for medical devices, software and robotics;
- evaluate the ISS using a multidimensional logic and promote the ISS as a national and international hub for the development and implementation of One Health strategies using an interdisciplinary and intersectoral approach;
- promote the capacity of the ISS as a reference point for ensuring preparedness (early detection and response) to counter health threats (not only SARS-CoV-2 but also, for example, emerging and re-emerging zoonoses) and for adopting control policies by enhancing the interdisciplinary and intersectoral strategies of One Health to support the NHS in a framework of international collaboration;
- carry out project activities for monitoring episodes of exposure to dangerous products, implementation of the Network between ISS, Ministry of Health and Poison Control Centres (*Centri Anti-Veleno*, CAV).

Inevitably, in light of the experience gained in the context of the COVID-19 pandemic, the role of the ISS in preparedness and its technical and scientific support in all areas of expertise during public health crises becomes a further element characterizing the three-year period being considered in this document.

In order to accomplish the general objectives described here, the organizational structure has been made more robust and modern thanks to the updating of the internal organization, to be pursued also by implementing an extraordinary maintenance of the Statute and of the Rules of Procedure (*Regolamento di Organizzazione e Funzionamento*, ROF) and subsequent regulations, and the technical-managerial infrastructures of the Institute have been adapted and strengthened.

The following objectives are to be achieved in the three-year period: plan, manage and enhance human resources as strategic keystone for achieving the objectives of the institution, also in relation to new working methods, new skills and the promotion of equal opportunities; increase the efficiency of the Institute by strengthening the programming, implementation, monitoring, and evaluation cycle; develop and implement tools for management control and for the performance cycle; re-engineer processes as a function of digital transformation, also through the adoption of standard procedures; spread the culture of quality; maintain high safety standards; update and strengthen the equipment, infrastructure and buildings of the Institute. These objectives will be taken up again in the chapter dedicated to the development of the internal context.

4.2 • Macro-objective 2. Strategic core of Italian health research

Scientific research for the promotion and protection of public health is a fundamental task of the ISS. Over the years, it has unfailingly been a core commitment of the Institute's action, which recognizes scientific research as an indispensable activity for providing decision-making and operational support in the context of the Country's healthcare environment.

The Institute's research policy is inspired by the principles of the European Charter for Researchers, which establishes the recognition of the researcher's profession, the importance of a stimulating research environment, the flexibility and at the same time stability of working conditions, the possibility of professional growth as well as an adequate salary and social security measures.

The ISS also promotes the principles of research integrity and encourages the communication and exchange of results in order to extend its visibility and impact to the entire scientific community from an "open science" perspective. In 2020, the PublISS institutional digital archive was developed, based on the open-source program DSpace, with the function of deposit and free access to internal scientific production, in compliance with the principles summarized in the acronym "FAIR" (Findable, Accessible, Interoperable, Reproducible), promoted by the European Open Science Cloud (EOSC), and with the integrity of research data. The initiative represents an important step in the process that the ISS started in 2008, and which finds full expression in the policy on the management of research results (scientific publications and data), which is expected to be adopted and made public by 2021.

The ISS also promotes the application of the "3R principle" (*Replacement, Reduction, Refinement*) in research and control activities, encouraging the development of all the methods that make it possible to replace the use of animals for testing and, where this is not possible, to reduce their number and maximize their well-being.

The promotion of scientific research therefore represents an essential element of this programming plan, to be implemented through general objectives such as:

- programs dedicated to the enhancement of ISS personnel, also through collaborative networks;
- actions dedicated to young researchers;
- updating and upgrading the Institute's equipment and IT infrastructure;

- development of support activities for national and international research;
- enhancement of research products through technology transfer.

The research activity of the three-year period is focused on main themes in the areas defined by the 7 macro-areas of activity of the Institute, consistently with the challenges identified in international and national documents of reference. Within this general approach, over the three-year period there will be an additional commitment across the 7 macro-areas in response to the challenge of the SARS-CoV-2 pandemic:

- *Health and environment*: this macro-area includes studies on the characterization of exposure to risk factors in various environmental settings, in living environments and in places where anthropogenic activities are carried out, as well as studies on the impact that environmental and climate risks have on health. The areas of intervention range from the quality of air indoors and outdoors, to water resources / integrated water cycle, to soil / waste, toxicological risk assessment and epidemiological research and surveillance on the effects and impact of environmental /social risk factors on populations. In this context, it is worth recalling the management by the ISS of the WHO collaborating centre (WHO Collaborating Centre for Environmental Health in Contaminated Sites) harmonising the activities concerning health and contaminated sites carried out by the ISS, the Ministry of Health, the Ministry of the Environment, the Higher Institute for Environmental Protection and Research (ISPRA), the National Environmental Protection System (SNPA) and WHO.
- *Drugs*: the activities of this macro-area have the aim of: promoting the development of new therapeutic approaches in the treatment of human diseases through pharmacological research and trials on experimental treatments; exploring, developing, and applying analytical methods to test the quality of drugs; assessing the appropriateness of using medicines in the post-marketing phase and surveillance on the safety of medicines, vaccines and substances of natural origin; preclinical and clinical evaluation of medicines for the purpose of authorizing registration studies and regulatory approval. In addition to focusing on human drugs, this activity will be further strengthened through partnerships with the Ministry of Health on veterinary drugs.
- *Communicable diseases*: this macro-area includes basic, clinical, translational and public health research in the field of infectious diseases, caused by viruses, bacteria, fungi, parasites and prions, including HIV / AIDS and other emerging pathogens. The persistence of the pandemic caused by the SARS-CoV-2 virus requires a constant focus on research on various fronts and this effort will be part of a more general approach where the pathogenic mechanisms of infectious diseases will be studied by using models in vivo, in vitro and ex vivo; the antimicrobial activity of drugs / molecules will be studied through the development and / or reformulation of molecules; and the development of new vaccines will be studied through the search for new antigens, vaccine models (subunit, DNA, mRNA), adjuvants and routes of administration for the prophylaxis of infectious diseases in both in vivo and in vitro preclinical tests on immunogenicity and efficacy.
- *Non-communicable diseases and rare diseases*. These studies focus on genetic and environmental causes, pathophysiological mechanisms, prevention, diagnosis and treatment of non-communicable diseases, including rare diseases and congenital anomalies, with attention also to gender, to eliminating inequalities, to the life-course perspective and to regenerative medicine. Activities include: research in oncology and molecular medicine;

health and gender; biomarkers and biological mechanisms of the main cardiovascular and endocrine-metabolic diseases; aging and phenomena of fragility and comorbidity; rare diseases, undiagnosed rare diseases and congenital anomalies; research on neurodegenerative diseases, including dementias, and demyelinating diseases; research on the biological basis, treatment and prevention of mental and behavioural disorders and associated pathologies.

- *Disease prevention, health promotion and global health*: Studies include research on the prevention of diseases, mortality and adverse events through descriptive and analytic epidemiological studies, also on specific population targets or those affected by diseases; the development and evaluation of activities that promote health in various scenarios, involving individuals or groups, also with regard to behavioural and substance addictions; research on the improvement of health systems, on the quality and safety of care, also in the field of transfusions and of organ, tissue and cell donation / transplantation; research aimed at improving health in both developed and developing countries, at combating inequalities in access to care; research on the health literacy of the population and development of actions to improve it; research and analysis for the development and dissemination of principles, standards and processes for the improvement of the quality and impact of research also from an ethical point of view.
- *Food safety and nutrition*: research activities are aimed at ensuring the healthiness of food and the adoption of appropriate eating habits, through research on the chemical and microbiological safety of food and its effects on human health; epidemiology and risk assessment in food safety and human exposure; activities to support investigations in food emergencies; the effects of different eating styles on metabolism and on health; nutritional strategies for the prevention of overweight and obesity, also from a gender perspective; food allergies and intolerances; clinical and preclinical trials on nutritional intervention.
- *Chemistry, radiations, innovative technologies and telemedicine*: this macro-area groups research work on the protection and improvement of health through the analysis and reduction of chemical and radiation risks, on the development and scientifically validated use of technological innovations and innovative therapies using biomaterials, nanotechnologies and substances of natural origin, also using multidimensional assessment tools through HTA activities, linked to the generation of scientific evidence through innovative methodologies and approaches (such as Big Data, digital technologies, “-omics” sciences). This is done through participation in institutional and targeted research projects in the context of European programs (e.g. Horizon). It includes studies on the development of methods for the characterization of chemicals and medical devices; for protection from ionizing and non-ionizing radiation and for the optimization of the medical uses of radiation; studies on clinical validation and multidimensional impact assessment to support the governance of health systems and care services with digital technologies; studies on the use of Big Data and Artificial Intelligence in making diagnoses; studies on the development of bioinformatics, biostatistics and physical-computational tools; studies on the advancement of methodologies, procedures and technological development of large scientific instrumentation in support of research; studies on Quality Assurance; studies on the creation of thematic laboratories for medical devices, for both research and surveillance purposes; and studies for the adequate use of technologies to support frailty and disability.

Furthermore, the ISS considers it strategic to promote research initiatives that cut across macro-areas, including, for example, the *RicercaItaliaAfrica* initiative where Italy cooperates with Africa on the objectives of: creating a stable and sustainable network of research activities on health; harmonize, attract and increase Italian public support in this field; and connect Italian health research activities to international agencies, institutions and initiatives to align its activities with the objectives of sustainable development.

In order to promote national and international biomedical research, the ISS will continue to support the activities of the three major European research institutions in the field of Biomedical Sciences and Health which are part of the European Research Infrastructure Consortium (ERIC) whose design and creation saw the contribution of the ISS in 2008: the European Advanced Translational Research Infrastructure in Medicine (EATRIS), the European Clinical Research Infrastructures Network (ECRIN), and the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI).

The ISS represents our Country in the governing bodies of European consortia, in synergy with the Ministry of Health and the Ministry of Research (<https://www.iss.it/reti-internazionali>). Thanks to the ERIC consortium and with the help of Member States, the European Commission intends to develop infrastructure for research in specific sectors which would be unfeasible and unsustainable by individual Member States; such infrastructure will offer competitive conditions and for effectively implementing Community research programs and enabling technological development.

In the context of European Research Infrastructures, the ISS participates in ELIXIR for performing high-intensity data analyses in the field of “life sciences” (www.elixir-europe.org, <https://elixir-italy.org/>), and in METROFOOD, created to harmonize scientific research in the area of food quality and safety and to promote the use of metrology in food and nutrition ().

Finally, the development of support activities for national and international research is considered a priority, through the strengthening and organizational redefinition of structures such as the Technical-Scientific Service for Research Coordination and Support, the office in Brussels and the Technical-Scientific Service of the Grant Office and Technology Transfer.

In this context, a further priority area for intervention is that aimed at fostering the culture of technology transfer and raising awareness among researchers towards the enhancement of their scientific know-how. The research body’s position with regard to the protection of intellectual property and patents has the aim of protecting the investments made in scientific research and discoveries.

Currently, the ISS is the owner or co-owner of 68 groups of patents for a total of 210 submitted applications. Of these, the ISS holds a share that is equal to or greater than 50% of 63 patent families (data updated to August 2020). The need for training activities addressed to researchers with the aim of contributing to the enhancement, communication and protection of research results was also recognized by the Ministry of Health which, among other initiatives, launched a training program called *TT School* in 2017 which is repeated every year.

Still in the context of the enhancement of technology transfer, A_IATRIS, the national network of the European Translational Research Infrastructure EATRIS, has developed a program of “itinerant workshops” aimed at delivering to the largest number of researchers belonging to the

Institutes of the A_IATRIS network, including the ISS, all the basic knowledge required to recognize, protect and enhance the results of their research work.

4.3 • Macro-objective 3. Essential node in the Italian, European and international public health networks

The ISS works to promote the protection of public health, also at European and international level, by contributing to the development of national and international public health strategies and biomedical research, by participating in networks, and through national and international partnerships. In particular, in recent years, the ISS has increased its collaboration with national, European and international networks and with EU institutions (European Commission, European Parliament, Committee of the Regions, Permanent Representation of Italy to the EU and EU Council-Presidency), with international organizations such as the G-20 and the OECD, thus becoming a dynamic player on the EU and international scene.

This commitment has been confirmed for the 2021-2023 three-year period.

The following activities have been planned at national and international level:

- coordination of and / or participation in interdisciplinary working groups for the definition of strategic national policies for promoting psycho-physical development and health in all ages of life, also by providing support to the activities of the Central Administrations (Ministries, Conference State / Regions), of the Regions and of local institutions;
- implementation of planning, coordination, training and supervision activities, in support of the Regions, for the purpose of upgrading the quality management systems in transfusion facilities and their alignment with national and European legislation;
- creation of a collaboration network between the central institutions, such as the Ministry of Health and the ISS, and the regional institutions, with the coordination of the Gender Medicine Reference Centre for the application of Law 3/2018 (Plan for the application and dissemination of Gender Medicine);
- implementation of projects and training activities within the healthcare network for patients suffering from congenital haematological diseases and the national networks of hematopoietic transplantation, banks for the storage of umbilical cord blood and innovative cell therapies;
- implementation of planning, surveillance, training and information activities within the national network of rare diseases; participation of the ISS in the activities and committees of the European Commission for the coordination of the European Networks of reference.
- strengthening the role as coordinator of national and international networks in food safety and veterinary public health, through the definition of an integrated organizational framework for the ISS structures called upon to act as coordinators, in particular, the National and European Laboratories of Reference (NRL and EURL);

- coordination of Multidisciplinary Study Groups for Quality Assurance in Radiological Sciences (Radiotherapy, Radiodiagnostics, Interventional Radiology, Nuclear Medicine) which involves all the Scientific and Professional Associations operating in the sector and all the IRCCS (Scientific Institutes for Research, Hospitalization and Healthcare) and Structures of the National Health Service;
- coordination of the Network of laboratories that control chemical products and support the Regions / PA and the Ministry of Health in planning the annual National Control Plan for Surveillance of the National Territory;
- implementation and development of effective integrated surveillance systems (microbiological, epidemiological, genomic) of the main infectious diseases that threaten public health, building on the experience gained in responding to the SARS-CoV-2 pandemic. In order to be comprehensive and reach out to all corners of the Country, these systems must be based on networks of microbiology laboratories and supported by networks of sentinel doctors, who collect clinical and laboratory data. To this end, the IRIDA-ARIES platform for the collection, analysis and sharing (between regional, national and European levels) of genomic data of microorganisms of interest in public health, including SARS-CoV-2, will be further strengthened and extended. The action of the ISS is aimed at aligning itself with Community surveillance systems, contributing data to the European and international networks (ECDC, WHO etc.), based on the experience gained during the COVID-19 pandemic;
- promotion of an integrated multi-sectoral and cross-border approach to global challenges (Cross-border One Health), through the MediLabSecure International Network (MLS, Mediterranean, Black Sea, Middle East and Sahel regions) and multi-country operational research for controlling arthropode-borne-viruses that are increasing because of climate and environmental changes;
- strengthening the health systems in Italy and in the world, also through international cooperation activities, to improve prevention and access, appropriateness, safety and quality of care;
- strengthening the role of the ISS in the network of OCCL (Official Cosmetics Control Laboratories) and OMCL (Official Medicines Control Laboratories), coordinated by EDQM (European Directorate for the Quality of Medicines), which see the participation of the National Authorities that carry out official analytical control activities and which are periodically inspected to verify compliance with the UNI / EN / ISO 17025 international standards; adherence to these standards provides for the adoption and maintenance of a certified quality system which – by ensuring the quality of the analytical tests performed on controlled drugs – creates a virtuous system for the protection of public health;
- participation in the HelpNet Steering Group of the network of European Helpdesks for regulations on substances and products;
- strengthening of the Italian liaison role with ECHA, and with other Agencies, European Authorities and Scientific Committees - EFSA, ECDC, EMA, EU-OSHA (*European Agency for Safety and Health at Work*), SCCS (*Scientific Committee on Consumer Safety*) – with the European Commission, International Bodies (OECD, UN), with Standardization

Bodies - UNI (Italian National Unification Body), CEN (European Standardization Committee) and ISO (*International Organization for Standardization*) - and with national Bodies and administrations, and providing support to the Ministry of Health and to the Regions;

- launching, within the framework of the Italian Presidency of the G-20 Health Summit, of an international initiative on the training of health professionals, which will be the subject matter of a dedicated webinar run by the Institute (10 March 2021);
- participation in Expo Dubai from October 2021 to March 2022 with a focus on strengthening international scientific cooperation by providing an analysis of the social impact of technological innovation in healthcare.

Also through its office in Brussels, the ISS will actively participate in setting the health priorities for the next 2021-2027 “Horizon Europe” framework program for research and innovation, the next 2021-2027 “EU4Health” public health program, the Next Generation EU plan, and it will also contribute to the definition of the related innovative health policies in the field of preparedness and management of health crises, vaccination policies, strengthening of innovative health systems, management and treatment of cancer, pharmaceutical strategy, policies for the defence of the environment, One Health approach against antimicrobial resistance.

The “Horizon Europe” program also includes new tools, which have as a common objective that of addressing global challenges, in line with the sustainable development goals. In particular, the Partnerships will make it possible to combine and coordinate a wide range of research and innovation activities in order to address common priorities jointly with Member States, the private sector, foundations and other stakeholders. Among the proposed partnerships, of particular interest for the mission of the ISS are: innovation of health systems; global health for Africa; the identification and assessment of chemical risks for human biomonitoring; and clinical and preclinical trials. For these initiatives, the ISS will actively work alongside the Ministry of Health and the MUR.

4.4 • Macro-objective 4.

An authoritative and independent leader in Italy, Europe and the world

The Institute is committed to strengthening its role as an authoritative and independent body of reference in Italy, Europe and the world for scientific activities and for health monitoring, regulation, evaluation and control as well as for training and information in public health.

Since its foundation, in addition to the research activities mentioned in the foregoing, the Institute has carried out a significant amount of surveillance, regulation, control, consultancy and inspection activities in its areas of competence: from communicable and non-communicable diseases, to the sectors of the environment, food, drugs (medicines, serums and vaccines for human and veterinary use), biomedical technologies and health systems. The ordinary activities carried out by the Institute have always been accompanied by interventions of an extraordinary nature related to health emergencies, at the request of central or regional administrations, for the development of methods of analysis, guidelines and surveillance systems.

The activities to protect public health that will be confirmed and expanded over the three-year period include: control and assessment of the quality of drugs (including blood products and vaccines); biological safety tests on injectable medicinal products and sterile medical devices and on in vitro diagnostic medical devices; regulatory activities in the field of medical devices, protection from ionizing and non-ionizing radiation; risk assessment in the field of nanotechnologies used in the biomedical field, food safety and veterinary drug; the safe use of substances through the coordination of evaluation activities in accordance with Regulation (EC) 1907/2006 (REACH: Registration, Evaluation, Authorization and Restriction of Chemicals); analytical checks on substances, mixtures and items for the safety of consumer products and consumer protection; Evaluation of active ingredients and biocidal products, Medical Surgical Devices (PMC) for marketing purposes; quality and safety of organ, tissue and cell donation and transplantation - including the promotion of blood donation on the occasion of the international “World Blood Donor Day”; monitoring the quality of genetic tests and neonatal diagnostic and screening investigations (of rare, metabolic and non-metabolic diseases) for the purpose of secondary prevention of non-communicable and communicable diseases.

Monitoring and surveillance systems will also be provided and updated with the aim of identifying potential hazards for public health at an early stage. Through the National Registers coordinated by the ISS, a monitoring system in line with European best practices will be provided, while at the same time harmonizing the processes on the national territory. The coordination of surveillance systems on risk factors for the health of children, adolescents and adults - as well as of pregnant women and new-borns - will continue to envisage training and support networks for professionals, estimate and describe the phenomena under study by collecting population data, analysing the data and producing knowledge useful for action, return the data and results to the Regions, circulate the data among the main stakeholders and provide guidance in support of prevention and health promotion. Indicators will also be provided for the evaluation of National and regional prevention plans, for the LEAs and for the New Guarantee System.

Over the three-year period, these activities will be consolidated, developing and offering training and scientific dissemination programs and interventions, aimed both at NHS professionals involved in health surveillance, prevention and promotion, and at non-health professionals engaged in the various areas of prevention and promotion of health, adopting interactive teaching methods for adults and focusing on providing solutions for the emblematic cases that health professionals have to deal with every day. With reference to training courses, since 2017 the ISS has been authorized to provide courses for school staff through the SOFIA-MIUR platform (Decree no. 4450 of 25 September 2017).

The public health activities of the PHACEE network, set up within the Central European Initiative, which brings together EU Member States with Countries that are not members of the EU, in particular the Balkan Countries, will also continue, along with the training activities in Global Health and Health of migrants in Italy.

In addition to the platform already described (Macro-objective 3), the ISS will actively participate in other initiatives of the G-20 Health Summit, in the areas of preparedness for public health emergencies, even in fragile international contexts, the One Health strategies and the SDGs. Further preparedness activities will be part of the “EU Scientific Advice Platform on COVID-19”, set up at the end of 2020 by the President of the European Commission to share, among Member States, the actions to combat the pandemic within the framework of the strategy called “A united front to beat COVID-19”.

With the Venice office of the European WHO branch, the ISS will participate in the drafting of the document: “The Italian Health Equity Status Report” (IHESR) on the factors that cause health inequalities in Italy.

Finally, the institutional tasks of the ISS also include the dissemination of evidence and information to citizens, NHS operators and to public health operators. In line with SDG 4 (Quality education: providing quality, equitable and inclusive education, and lifelong learning opportunities for all), national and international activities will be carried out through residential and distance learning courses (FAD), thematic websites (e.g., ISSalute) and research activities on the health literacy of the population with actions being developed to improve the population’s health literacy.

The role of the Training Service will continue to focus on offering continuous training designed to respond adequately and promptly to training and refresher needs, in line with emerging health objectives at national and international level. The continuous updating of IT infrastructures and platforms will ensure the smooth running of training and information activities.

4.5 • Macro-objective 5.

An organization that is open to the citizenry and to Italian and international bodies and institutions

The Institute offers direct services to citizens, to Italian and international institutions and in general to all stakeholders through actions and initiatives that also support the image of Italy in the world.

The first objective is to increase interaction and collaboration with the main institutional actors of the NHS, such as the Ministry of Health, the National Agencies and the Regions, with public research institutes, in particular with their bodies such as the Board of Presidents (ConPeR) and the Board of General Managers (CoDiGer), and with universities. At the same time, attention will be paid to contacts and synergies with professional associations and scientific societies.

The ISS is increasingly committed to offering citizens direct and transversal services to encourage the circulation of unbiased and uniform information and enabling its good use, to guiding the citizenry along the national and international healthcare paths and to encouraging the adoption of healthy lifestyles and healthy behaviours.

Various tools which have already been referred to in Chapter 3 contribute to this goal, such as: Toll-free Telephones, the ISSalute Portal, the Public Health Library and the Museum of the ISS. Citizens also have access to all the information material displayed on the stands at the cultural events in which the Institute participates.

Through its various instruments the Institute addresses the press to provide people with correct information on all the issues over which the Institute has competence.

The ISS operates specific programs for primary schools, by providing training courses within the context of the “Pathways for Cross Skills and Guidance” of the Ministry of Education and it organizes initiatives for the “European Researchers’ Night”.

Over the three-year period, the Institute intends to strengthen its role as an organization open to citizens and to national and international bodies and in this sense the experience gained during the SARS-CoV-2 pandemic represents an interesting model which deserves being strengthened and replicated also through:

- a systematic dialogue with the aforementioned institutional actors and participation in various advisory boards on the various issues;
- information and communication programs and interventions capable of responding adequately and promptly to the training and refresher needs of professionals who work in areas of promotion and protection of public health, and emergency workers;
- meetings, actions and programs aimed at Regions, National Agencies, scientific societies, professional associations and trade associations, citizens and patient associations;
- information dissemination instruments and programs for citizens and the schools.

5 • Development of the internal context

Human resources are the very heart and engine of an institution like the ISS and of its programs and are instrumental to its activity and authority. Competence, creativity, rigorous respect for methodology and passion, however, are not enough if they are not features of an organization that promotes and enhances its resources and makes available support structures that are lean and respond readily to its needs.

For this reason, in the 2021-2023 three-year period, special attention will be paid to extraordinary maintenance of the internal organization, starting with the Statute, the ROF and the regulations, with particular attention to the transformations deriving, among other things, from the digitization processes. In this context human resources policy is a fundamental asset that strategic management is called upon to enhance. An important tool will be the involvement of all stakeholders, each within the scope of their individual prerogatives.

In addition, special attention will be paid to the cycle of human resources, from recruitment to the upgrading and enhancement of skills, career paths, incentives, and exit from the Institute, all in a context where safety is inherent in the system. Exchanges between national and international institutions will be encouraged, and the development of organizational well-being will gradually become a characterizing element of the life of this Institute.

5.1 • Instrumental resources

5.1.1 • Wellbeing of the organization

In accordance with the description provided so far and in compliance with the Directive of 24 March 2004 which introduces measures for the improvement of organizational well-being in the Public Administration (the so-called “Welfare Directive”), the human resources management plan imposes a series of actions which were included in the specific plan approved in December 2019, and which are summarized as follows:

1. survey the opinions of workers to assess and improve their well-being;
2. increase the motivation of workers through incentives, developing a sense of belonging to the Institute, also by means of refresher courses;
3. create opportunities for discussion to improve relations between managers and staff;
4. create internal communication systems to spread the culture of participation.

With resolution no. 7 of 19 November 2019, the Board of Directors of the ISS approved the “2019-2020 Action Plan on Organizational Wellbeing and Integrated Health Promotion Program in the ISS”, as an integral part of the action plan of the Institute.

This plan, which is totally new since nothing similar had ever been done before, provides for a long-term, integrated and multi-component program in support of the health of the staff and is broken down into specific projects to be developed and implemented gradually and systematically. The plan includes actions under the following headings: ISS plastic free; ISS recycling; ISS smoke free; Well-being of the staff; ISS mobility. These actions are characterized

by an ecological approach and aimed at the active and inclusive participation of all stakeholders. The interventions, connected to the actions indicated in the National Prevention Plan, comprise several levels: policies, working environment, health promotion, and the fight against risk factors.

To facilitate the implementation of the plan, the ISS set up the Wellbeing Working Group (decree of the President of 6 February 2020), which immediately adopted a number of actions.

The COVID-19 emergency, with its priorities, has obviously caused a delay in the implementation of the planned actions and it has therefore been necessary to postpone some of the planned actions hence including them in the 2021-23 three-year period.

As a result of the impact of the pandemic on the organization of the Institute's work and also considering the stress it has caused for the workers, the Wellbeing Working Group, the Single Guarantee Committee and the Mobility Manager will develop actions to strengthen the plan.

5.1.2 • Information technology

The ISS is equipped with an IT Service, which has the task of supporting and providing Information and Communication Technology (ICT) services for the functioning of the Institute and to encourage the engineering of scientific research on health matters, which is the core business of the Institute.

During the three-year period of this plan, the IT Service of the ISS will pursue the objective of continuing the process of infrastructure renewal and upgrading that had been started in previous years.

In particular, in the course of 2020 the Institute equipped itself with a professional system for remote access to intranet IT resources, through a system consisting of a pair of VPN appliances which provides connectivity simultaneously to a thousand users scalable with high reliability up to 2,500 users, and with a bandwidth of 1 Gbit /s. This system proved to be essential during the pandemic because it enabled the staff to continue to work and carry out research activities from home.

Digital Transformation has ushered in a new culture and new development opportunities.

And indeed, in the three-year period considered, the ISS will continue the digitalization process where information sharing is key and is made possible by using advanced collaborative tools, including the cloud, with the aim of:

- improving administrative efficiency;
- simplifying the approval process;
- increasing transparency;
- reducing time and costs.

This trend will be accompanied by the completion of the dematerialization process.

In this connection, the experimental phase of the pilot project of profiling and computerized registration of applications for participation in internal recruitment processes will start soon and will subsequently be extended also to public competitions. The SIGLA platform (*Sistema Informativo per la Gestione delle Linee di Attività*: IT System for the Management of Business

Lines) of the National Research Council (Consiglio Nazionale delle Ricerche, CNR) will be used for this purpose.

Another significant element, which constitutes the development matrix for the three-year period, is IT security, with the establishment of a Security Operations Centre (SOC), which will monitor and define the processes for managing incidents so as to endow the IT infrastructure of the Institute with an adequate level of resilience.

5.1.3 • Simplifying administrative procedures through digital transformation

In recent years, our Country has stepped up the transformation and innovation of services to citizens and businesses with a view to simplification of procedures through the use of digital technologies.

The digital transformation of production and management contexts makes the system more efficient, but above all it shortens the distance between the Public Administration and the users, as well as facilitating access to services.

The push towards digitalization does not only consist in the construction of infrastructure and the diffusion of IT tools to be used by the Public Administration, it is also a new way of approaching innovation and organization.

The technological approach must be supported and accompanied by precise strategies aimed at changing the processes, models and working practices that characterize the organization, enabling it to evolve digitally, transforming the culture, management and operations. The first step is reorganization of the structure by introducing or training professionals with specific legal and organizational technological skills.

The digitalization process of the Public Administration has two main norms of reference: the Digital Administration Code, which sets the general policy and delegates the technical and operational regulations to the Guidelines (which has been updated several times), and the 2020-2022 three-year IT plan of the Public Administration approved with DPCM of 17 July 2020, which defines the operational strategy for the development of public IT and which is to be updated annually.

The roll-out of the digital administration continued with Law no. 120 of 11 September 2020, which converted, with amendments, Decree-Law no. 76 of 16 July 2020 (so-called Simplification Decree), containing urgent measures for simplification and digital innovation.

In particular, the next IT three-year plan of the Institute will provide for:

- implementation of the cloud first principle, both in technological terms (microservices architectures, etc.), and in terms of the acquisition of supply services in the SaaS form where possible, which is preferred over the direct management of applications;
- compliance with the obligations of the Digital Administration Code (*Codice dell'Amministrazione Digitale*, CAD) regarding Open Source so as to maximize the reuse of software developed on behalf of the Public Administration;
- monitoring of services through Web Analytics Italia, a national open-source platform that offers statistical surveys on useful indicators for the continuous improvement of the users' experience;

- access to services by citizens and companies using the SPID and making available the pagoPA payment system so that payments can be made by citizens and companies;
- data management policy enabling public administrations to share data for institutional purposes, and reuse of data for commercial and non-commercial purposes, according to the Open Data paradigm;
- accreditation process with the Agency for Digital Italy (*Agenzia per l'Italia Digitale*, AGID) as a “Group A” Data Centre infrastructure to verify the feasibility of it becoming one of the eligible infrastructures to be used by the National Strategic Poles;
- training courses for ISS employees on Cyber Security Awareness issues, to increase awareness and mitigate the risks associated with potential cyber threats.

The ISS intends to develop its digital strategy and consolidate the creation of a process focused on the adoption of application solutions functional to the computerization of administrative procedures.

The completion of the dematerialization process will improve the quality of the interaction with other public administrations, with stakeholders and with citizens, thus improving the performance of the Institute.

During the next three-year period, the instrumental and IT infrastructure of the ISS will be updated and strengthened and structural adaptation will continue, with a series of renovations and interventions as required by the legislation in force.

In particular, the ISS will equip itself with:

1. a decentralized registration protocol model. All the structures of the Institute will be enabled to register the documents over which they have competence;
2. an IT procedure whereby the flow of certified mail (PEC) of the structures can be integrated with the Central Protocol of the Institute (Numix);
3. a software for filing documents and sending them to the other structures of the Institute (Modix);
4. a progressive systematic approach to the transformation of processes at the level of the Central Administration, the Departments, the Centres and the Technical-Scientific services;
5. a management system ensuring security of the information present on the IT platforms of the registers and surveillance systems.

During the review of the ROF, a special office for digital transformation will be set up, led by the Responsible for Digital Transition (*Responsabile per la Transizione al Digitale*, RTD).

5.1.4 • Data protection

During the three-year period in question, the following activities will be carried out in order to fulfil the obligations laid down in Regulation (EU) 2016/679:

1. Continuity in the adoption and implementation of technical and organizational measures aimed at demonstrating that data processing is carried out in accordance with Regulation (EU) 2016/679 (Updating the privacy policy regarding the Internet, updating the data processing Register, implementation of the “Risk Analysis” document, internal policy

regulation on the management of data breaches, adjustment of contractual clauses both with regard to third parties and to internal relations, preparation of FAQs on the processing of the Institute's data) ;

2. Design and implementation of adequate data protection policies aimed at obtaining:
 - a. a constant and effective analysis of personal data protection activities regarding the data collected by the surveillance systems and registers, the data referred to in the Decree of the President of the Council of Ministers of 3 March 2017, and the data whose collection and management is not covered by the mentioned regulatory provision;
 - b. constant monitoring of the risk management processes of processing and of personal data processing activities, in order to maintain the effectiveness and efficiency of the Institute's "privacy compliance" as needs change in the delicate context of the field of scientific research;
 - c. adoption of the measures and activities necessary to equip the ISS with a technological architecture that ensures that the confidentiality, integrity and security of the information and personal data collected in accordance with the objectives of the Institute will not be breached;
3. Design, implementation and achievement of ISO/IEC 27001 certifications for data security management from a logical, physical and organizational point of view.

5.1.5 • Diffusion and publication of the guidelines containing rules on data processing, transfer, sharing and consent

A section will be created dedicated to the dissemination and publication on the Institute's Intranet of the guidelines containing clear rules on the processing, transfer, information sheet and consent of data in accordance with the provisions on data protection set forth in EU Regulation 679/2016 (known as GDPR, General Data Protection Regulation). A new section will be set up on the Institute's website to publish information about data protection (GDPR).

During the COVID-19 emergency, surveillance tasks were assigned to the ISS, which prepared an explanatory document on privacy protection, as a tool to understand the context in which personal data processing takes place. This document could be a point of reference for the management of similar databases.

5.1.6 • The ISO 27001 certification process

The goal is to set up an Information Security Management System (ISMS) at the Institute, that complies with the ISO 27001 standard. The ISO/IEC 27001 IT security standard defines the requirements for setting up and managing an ISMS, and it includes aspects relating to software, hardware and organizational security.

The certification body will review the entire documentation on the ISMS and verify that the controls listed in Annex A of the Standard are effectively and efficiently implemented. Subsequently, audits will be performed to verify the procedures in practice and if the implementation is found to be satisfactory, the ISO certification will be issued.

5.1.7 • Technical infrastructure, planning the relevant investments and logistics

During the 2017-2019 three-year period, a huge effort was made to bridge the technological gap that had been built up in the previous fifteen years. An important part of the large instruments managed centrally by the Core facilities Service (*Servizio Grandi strumentazioni e Core facilities*, FAST) was renewed, as well as those supplied to the various Technical-Scientific structures.

In the 2021-2023 three-year period, this renewal effort will be continued and completed so that the Institute's technological functionality will be satisfactory. Such condition will then have to be maintained through the periodic updating of all instruments and equipment and new platforms will have to be introduced as they become necessary.

The purchase and management of technical-scientific equipment have been rationalized and optimized through the creation of the FAST Service, which will allow a significant increase in the scientific productivity of the instruments while halving maintenance costs. Technological updates are supported thanks to the funds for capital expenditure that the Institute receives every year from the Ministry of Health. A procedure has been developed which makes it possible to use these funds in a coordinated and efficient manner. In brief, the Advisory Committee for Core facilities (*Comitato Consultivo per le Grandi Strumentazioni*, CCGS), made up of representatives of all the technical-scientific structures that use large equipment, collects and discusses the requests made by the Structures. The Committee examines the requests and where possible, merges them, and defines a priority list of purchases. The list thus obtained is sent to the Core facilities Commission, appointed by the Director General, which draws up a final list of recommendations and sends it to the Director General, who submits it to the Ministry of Health.

The funds indicated in Table 3 will be available in the 2021-2023 period for the purposes described above.

Table 3. 2018-2021 amounts for capital expenditure

Capital expenditure	Amounts in euro
2018 (carried over)	1,600,000
2019 and 2020 (delivered together in 2020)	3,882,000
2021 (estimated)	1,900,000
Total	6,282,000

Part of the funds will be used to purchase the large instruments managed by FAST as per the time schedule in Table 4.

Table 4. Time schedule of the installation of large equipment managed by FAST of the ISS

Instrument	To be installed in:
MRI 7T for small animals with cryoprobe	2021
High resolution NMR spectrometer	2021
Orbitrap Mass Spectrometer with nano HPLC	2021
Electronic paramagnetic resonance spectrometer (EPR)	2022
High-resolution transmission electron microscope	2023

The remaining funds will be used to renew the average-sized and large instruments supplied to each Technical-Scientific Structures.

In 2020, the Administration allocated 700,000.00 euros for the acquisition of small equipment with the aim of improving and maintaining technological functionality; for this reason, the mentioned endowment was increased to 1,500,000.00 euros for 2021.

The Institute also found it necessary to expand its capacity to conduct scientific research with the highest levels of quality and safety by strengthening the laboratories where class 3 biological agents are handled. For this purpose, a BSL3 biological containment laboratory is being built in a transportable structure which will initially be positioned on the premises of the Institute but it can be moved as needed.

Always with a view to implementing the strategy aimed at containing current expenses, while guaranteeing the required functionality standards and following intervention priorities in accordance with available resources, interdisciplinary laboratories are to be set up, whose instruments and systems as is being done with the controlled area for the cryopreservation of biological material.

At the same time, it is deemed necessary to improve the rooms used for training and dissemination activities, in which the Institute is increasingly involved, including the organization of national and international conferences, workshops and seminars. The upgrading will be completed over a three-year period during which 4 multimedia rooms will be restructured.

In 2020, activities were started for the creation of a Control Room for coordinating the institutions involved in the adoption of measures to contain the COVID-19 pandemic and more generally to contain any critical health situation that may emerge.

In consideration of the structural characteristics of the buildings included in the ISS complex, whose construction dates back to over 80 years ago, and the presumable costs for upgrading them, a procedure has been started to define the feasibility of building new headquarters for the Institute.

5.2 • Organization and quality

5.2.1 • Anticorruption and transparency measures

With regard to the prevention of corruption, the Institute has been engaged for some time in the adoption of the mandatory Three-Year Plan for the Prevention of Corruption and Transparency (*Piano Triennale della Prevenzione della Corruzione e della Trasparenza*, PTPCT) and of the ensuing obligations, pursuant to the provisions of Law 190/2012. The analysis and implementation of the rules on the prevention of corruption is a process that has evolved and that has progressively been refined, reaching thorough levels of understanding and implementation.

Thanks to this commitment, the Institute is engaged in constantly monitoring and reviewing the entire corruption risk management cycle, which, due to its dynamic nature, requires being constantly updated. In this context, with the help of an IT system created entirely through internal resources, a constant review will be made of the processes and phases that make up the

scientific and administrative activity of the Institute, the risks will be constantly reassessed and the prevention measures will be constantly monitored in order to confirm their suitability. The IT platform will represent the first anti-corruption database, constituting the precise summary of all the processes of the internal structures of the ISS.

In accordance with the provisions of Law 190/2012 regarding the necessary correspondence of strategic objectives regarding anti-corruption and transparency between PTA and PTPCT, in the light of the results achieved, and with a view to the constant improvement of the corruption prevention strategy, it is deemed necessary to achieve the following strategic objectives for the 2021-2023 three-year period:

- *Objective 1 - Anti-corruption. IT platform for the management of the entire corruption risk cycle*

Implementation of the application that allows the persons in charge of the Structures to report / self-certify the measures they adopt to contain the risk of corruption. The RPCT, as administrator of the platform, and being able to follow in real time the progress of the data entry by the Structures involved, will, as required by law, on the one hand constantly monitor the implementation of the measures, and on the other review the operation of the system as a whole at scheduled intervals.

Duration: annual

- *Objective 2 - Anti-corruption. General and specific training program*

Agreement with the National Administration School for the management of targeted training for ISS staff, promoting the growth of technical and behavioural skills of employees in the field of corruption prevention.

Duration: annual

- *Objective 3 - Anti-corruption. Consultation / Communication Program*

In accordance with the guiding principle of “widespread responsibility”, promoting internal communication activities by the RPCT and the other parties involved in the corruption risk management cycle. The communications will focus on the actions taken and to be undertaken, the tasks and responsibilities of each individual and the expected results.

Duration: annual

- *Objective 4 - Anti-corruption. Staff Rotation*

In compliance with the provisions of the National Anti-Corruption Plan which provides for the rotation of personnel operating in the sectors most exposed to the risk of corruption, personnel rotation will be started. Rotation must also and above all be understood as an organizational criterion that contributes to expanding the knowledge and professional preparation of the workers.

Duration: two years

- *Objective 5 - Anti-corruption. Monthly monitoring of transparency levels*

Continuous monitoring of the Transparent Administration section on the institutional website and drafting of a monthly report on missing data. It is essential that the documents, information and data subject to mandatory publication pursuant to Legislative Decree 33/2013 are made available promptly by the organizational Structures, in accordance with the provisions of the Plan, and published by the Data Disclosure Manager. Monthly

monitoring will allow to constantly check compliance with the law, avoiding unnecessary requests for civic access.

Duration: annual

Special emphasis must be placed on compliance with the rules on personal data, ensuring the rigorous balance between the dissemination of information and respect for privacy. In this sense, an indispensable contribution will be ensured by constant cooperation with the DPO of the Institute with which there must be constant interaction, in order to implement the provisions, among other things, of this document.

5.2.2 • Management control of strategic activities and of quality

Planning and management control are essential elements through which strategic guidelines and operational management policy are set up to achieve the objectives set by the Institute in its planning effort.

Starting from the last months of 2019, the Institute launched a process for the full implementation of management control also through the development of an in-house software product for the management of the entire performance cycle. A training course is being planned, which will be progressively rolled out to the entire internal staff of the Institute, aimed at spreading the culture of defining objectives, measuring results and analysing deviations. In the 2021-2023 period, while continuing the initiatives under way, action will also be taken to develop an approach whereby the ISS strategy will be aligned with the operational management so as to ensure that each line of action taken is matched with the necessary human, IT and financial resources. The aim is to progressively overcome the logic of working in “silos” and spread out participation so that people feel they are part of a project, of a vision to which each of them can contribute.

In summary, the general strategy will have as its point of reference the creation of “public value” (Figure 6) in favour of its stakeholders and of the citizens.

Alongside this action, the ISS aims to improve the quality of the management processes of the Institute and implement a Quality Management System (QMS) that originates from the existing QMS of the Conformity Assessment Bodies (Test Laboratories, Notified Body, Provider of interlaboratory assessment tests and external quality control, etc.) accredited, certified or otherwise operating in compliance with international standards on QMS; for this purpose it aims at standardizing and harmonizing the general processes and the systematic adoption of a continuous quality improvement approach. In this perspective, particular attention will also be paid to the management of procurement and tenders, and to monitoring that the required standards are complied with.

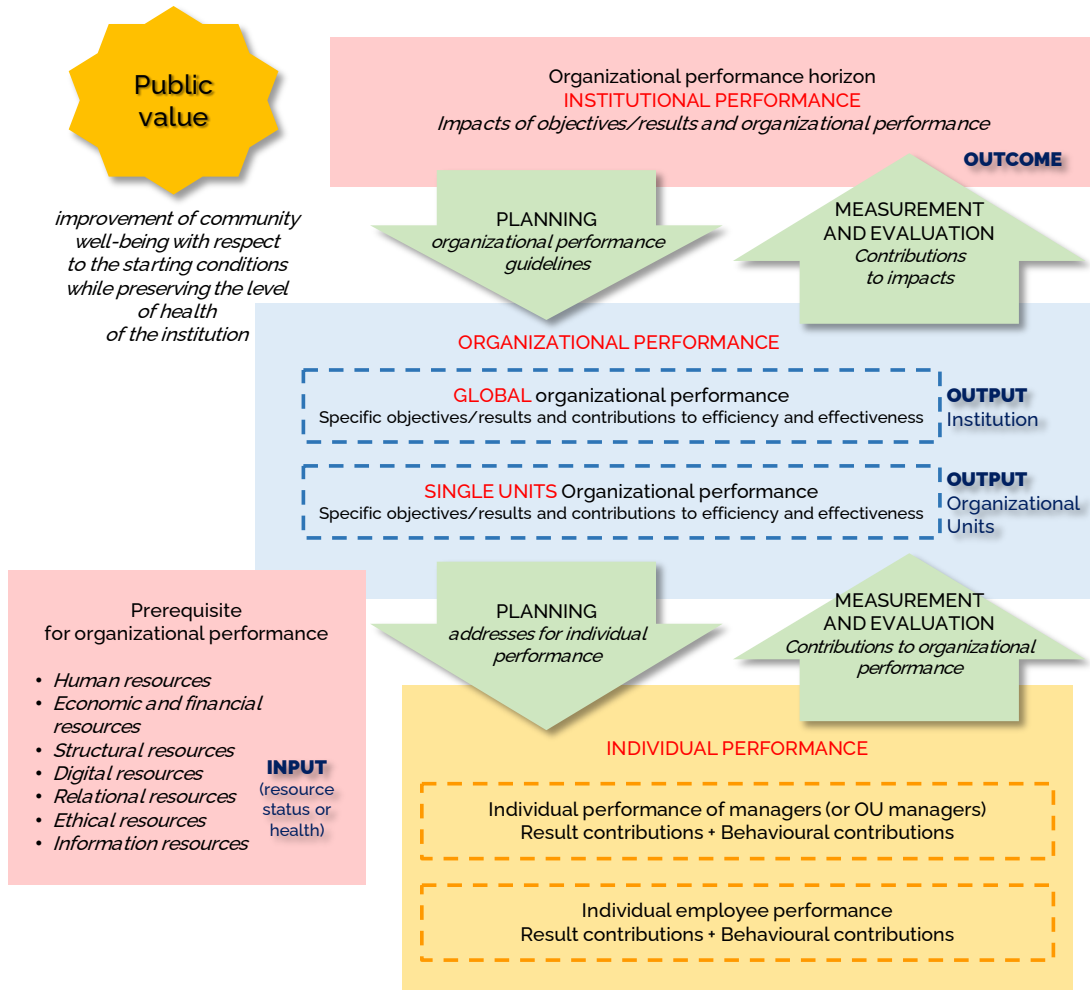


Figure 6. Strategy for the creation of public value

5.2.3 • Safety

The Plan of activities of the Occupational Health and Safety Service pursues the following objectives:

- improving the protection of health and safety in the ISS workplaces;
- implementation of the management system for health and safety at work;
- definition of rules and procedures, with the aim of achieving defined objectives.

In line with the contents of the 2017-2019 three-year plan and, as regards the micrologistics interventions for the protection of health and safety, the Occupational Health and Safety Service has updated the Risk Assessment Document in collaboration with groups of technical experts trained by professionals of the ISS. This activity entailed a cross-fertilization of the knowledge present in ISS, which was put at the service of the health and safety of the workers themselves, in relation to chemical-biological issues and to work-related stress. Training activities on aspects related to the pandemic scenario that has affected the activity of the ISS completes the first objective of improving health and safety (Table 5).

Table 5. Health and safety in the workplace: the strategic objectives, actions and objectives of the ISS for 2021

Strategic objective	Action	Objective for 2021
Implement a management system for health and safety in the workplace; define rules and procedures with the aim of reaching defined objectives	Rolling out the management system	Mapping of activities
		Operation of the new Risk Management software
		Definition of the main procedures
		Definition of the operational instructions
		Checking and reviewing the system
Improve health protection and safety in the workplace at ISS	Training program on health and safety at work	Updating the general and specific training of the staff (Specific and general training for the COVID-19 emergency)
		Updating smart working training
	Management of the COVID-19 pandemic context in relation to the role of ISS and to its institutional activities	Updating the ISS COVID Plan with reference to the evolution of the pandemic
		Keeping the Risk Assessment Document updated as working activities change

Following the update, the Directorate General has decided to undertake a verification process for the implementation of a health and safety management system in the workplace. Before implementing the system, a Gap analysis was performed, the training of the Safety Managers was updated and a system of proxies was defined.

In line with what was done in previous years, in the 2021-2023 three-year period the Occupational Health and Safety Service will continue to support management in the design, implementation, verification and review of a management system that is to comply with the minimum requirements defined by ISO 45001.

The UNI 45001 standard provides the Company with a structured approach to planning, implementation and management. This management system is structured to be compatible with ISO 9001 and ISO 14001 standards. The mapping of the activities carried out for controlling management and the anti-corruption plan, constitutes an excellent first step. The management systems of activities present in some Structures, are adequate and comply with national and international standards, such as UNI CEI EN ISO/IEC 17025:2018, ISO 17043:2010, ISO 35001:19, UNI CEI EN ISO 17034:2017, EN ISO 17021. This warrants the implementation and management, in parallel, of an integrated system for quality, the environment and safety.

Adapting the all ISS to the standard that establishes a quality management system in accordance with ISO 9001:2015 is an important objective of organizational improvement in all areas of activity.

The updating the professional training on smart working, especially with the persistence of the COVID-19 emergency, is a priority activity of the Occupational Health and Safety Service.

With regard to the updating of the Risk Assessment Document, a technical group will be set up to address the problem of logistics.

In the 2021-2023 three-year period, the Occupational Health and Safety Service will continue the implementation of the management system for health and safety at work and the definition of rules and procedures with the aim of achieving the objectives defined by the Institute in its areas of specific competence, by creating: a map of activities, by implementing the new risk management software, by defining the main procedures and operating instructions, and by constantly checking and reviewing the system.

Furthermore, in the 2021-2023 period, the improvement of health protection and safety in the workplace will be ensured through both general and specific training and refresher courses, for instance on the COVID-19 emergency, on the management of the pandemic context, and on smart working.

In addition, the Risk Assessment Document will be updated as a result of the changes made in working activities and of the new logistics that will be introduced.

In the 2022-2023 two-year period, also thanks to the evolution of the legislation, an integrated system will be implemented, with the aim of:

- achieving a single definition of the business context, of the policy and of integrated objectives;
- making a single assessment of the applicable risks and possible opportunities for all the requirements of the integrated standards;
- improving the corporate culture and human resources at all levels;
- improving the efficacy of pro-active responses to impactful situations;
- achieving a greater perception and awareness of the need to comply with mandatory requirements, also in the application of the organizational management model;
- reaching a single monitoring system and audit plan showing all applicable requirements;
- making sure all stakeholders perceive the Institute as a dynamic organization, attentive to the mission, to its employees, and to all applicable, mandatory and contractual requirements.

5.3 • Financial resources

The year 2021 confirms the positive trend already seen in 2020.

The structural equipment has increased by:

- i. € 4,000,000.00 (pursuant to Decree-Law no. 18 of 17 March 2020, relating to “Measures to strengthen the national health service and provide economic support for families, workers and businesses in relation to the epidemiological emergency associated with COVID-19”);

- ii. € 11,233,600, as laid down in the Budget Law 2021 (Law no. 178 (472) of 30 December 2020)¹.

The aforementioned positive trend is also confirmed for the years 2022 and 2023, as shown in Table 6.

Table 6. Total financial resources of the ISS in the 2021-2023 three-year period (contribution to the ISS item 3443 – Ministry of Health, 2021-2023 budget)

2021*	2022**	2023**
123,941,351.00	127,941,351.00	127,941,351.00

* the contribution has increased by € 11,233,600; ** the contribution has increased by € 15,233,600

These resources are compounded by those deriving from the research projects in which the Institute participates, and by the research funds for capital expenditure earmarked for the purchase of scientific equipment, as described earlier in this Report.

The actions outlined in this Plan will be implemented thanks to the availability of these funds.

In particular, on an annual basis, the Institute will be able to:

- a. fund an internal research tender;
- b. fund a research tender addressed to Young Researchers (using the ‘5-x-1000 funds);
- c. investments to upgrade infrastructures for the safety of the workplace and of the premises;
- d. investments for the purchase of new scientific equipment, using both the specific agreements with the Ministry of Health (for the purchase of large equipment), and by allocating a portion of budgeted resources for the renewal of small equipment;
- e. upgrading the IT platform for the training of NHS workers.

¹ It is hereby pointed out that the ordinary contribution by the State in favour of the ISS has increased by 11,233,600 euros for the year 2021, by 15,233,600 euros for the year 2022 and by 19,233,600 euros per year starting from 2023. As regards charges, there will be a reduction in the spending authorization as per Article 12 (2) letter a) of Legislative Decree no. 502 of 30 December 1992 for 11,233,600 euros per year starting from 2021, and, as regards 4 million euros for 2022 and 8 million euros per year starting from the year 2023, there will be a corresponding reduction in the Fund for structural economic policy interventions, referred to in Article 10 (5), of Decree Law no. 282 of 29 November 2004, converted, with amendments, into Law, no. 307 of 27 December 2004. 473. The decree of the Minister of Health, in agreement with the Minister of Economy and Finance, includes additional resources to the budget of the Ministry of Health to be used to supplement the ordinary State contribution, referred to in paragraph 472, to the Istituto Superiore di Sanità with a corresponding reduction of the budget items.

6 • Recruitment Plan

6.1 • Summary of the 2018-2020 PTA

The main resource of the Institute, in addition to its scientific know-how, is its human resources, which have always been placed at the centre of the Institute's governance policy and of the management policies of the last few years, with an emphasis on the professionalism of its researchers. In particular, in drafting the PTA, attention has been paid to developing the personnel policy in harmony with all the other activities of the Institute. As is known, the entry into force of Legislative Decree 218/2016 provided a policy framework, especially Articles 7, 9 and 12 (4), which have linked human resources to the planning activities, thus fulfilling the vision that has transformed the concept of staff as a static prerequisite, into a dynamic element linked to actual needs.

The above-mentioned provisions have enabled the management of human resources and the implementation of the plan to comply with the provisions of the Institute's Statute (which, in Article 16 (3) of the Ministerial Decree of 24 October 2014, requires that three-year plans be drawn up for human resources) and of ROF (which, in Article 24 (4) of the Ministerial Decree of 2 March 2016, requires that a three-year plan for human resources be attached to the PTA). As a result of these provisions, substantial innovations have been made in human resources, as reported in the following.

This is the context in which the first PTA was drawn up which established the general guidelines of activities, determined the objectives, priorities and resources for the three-year period, defined the expected scientific and socio-economic results, as well as the human resources needed, and the instrumental and financial resources for each action plan and each project included in the Plan.

The proposed update of recruitment needs, therefore, was the implementation tool of the above-mentioned three-year plan for the year being referred to.

Indeed, the scrolling of the Plan, for the 2018-2020 three-year period, responded to the need, that was strongly felt by the Institute, to:

- complete the "stability" process initiated with the extraordinary recruitment program implemented in 2017;
- encourage career progression of the Institute's staff, by implementing the advancement mechanisms laid down in the level II collective bargaining contract currently in force;
- recruit new professionals for the technical-scientific areas, also anticipating the professional profiles that the Institute may need in the future.

Resolution no. 1 attached to Minutes no. 27 of the Board of Directors of 9.10.2018 confirmed the purposes and objectives identified in the aforementioned 2017-2019 PTA, and highlighted the need to recruit new human resources in accordance with the needs identified in the three-year Plan (so as to make it possible to achieve the objectives that had been set in the past).

With resolution no. 1 attached to Minutes no. 30 of the Board of Directors of 27 March 2019, the guidelines of the 2018 hiring plan were taken up again and specific recruitment procedures

were drawn up according to the criteria identified in the previous resolution of the Board of Directors no. 1 of 09.10.2018, which were submitted to the supervising Ministry for its approval. In compliance with the objectives of simplifying and rationalizing the Institute's resources and activities, and of enhancing the existing professional staff, the scrolling of the Hiring Plan extension of the recruitment plan was arranged through the adoption of 5 separate resolutions on the recruitment procedures for the implementation of framework resolution no. 1 (respectively resolutions 1a, 1b, 1c, 1d, 1e, for planning the recruitment of human resources, pursuant to Article 7 of Legislative Decree 218/2016), in accordance with the criteria mentioned above.

In particular, the adoption of the following procedures was approved:

- Recruitment in pursuance of Article 20 (1), of Legislative Decree 75/2017 by publishing the indication of interest attached to the resolution;
- Recruitment in pursuance of Article 20 (2), of Legislative Decree 75/2017 by starting procedures for the recruitment competition;
- Implementation of 100 career advancements in pursuance of Article 15 of the National Collective Labour Agreement (CCNL) 7/4/2006;
- Announcement of a reserved procedure in pursuance of Article 22 of Legislative Decree 75/2016 for 30 posts;
- National public competition for 10 posts.

On this point it should be noted that, while the reserved procedure provided for by Article 20 (1) of Legislative Decree 75/2017 was defined in the last quarter of 2019 and the preparatory work for the implementation of the other competition procedures continued, in 2020 the problems raised by the pandemic (as pointed out in the premise) caused delays and made it necessary to postpone the deadlines for the competitions defined in the previous PTA.

It is worth pointing out that the so-called *Mille proroghe* decree extended to 31 December 2021, deadline for the completion of the procedures concerning the candidates eligible for the provision contained in Article 20 (1) of the Madia Law.

As for the professional development opportunities for Researchers and Technology experts (who respectively have an organization chart containing three levels), in light of Ruling no. 8985/2018 of the Court of Cassation regarding the economic advancements referred to in the contract provision of Article 15 CCNL 7/4/2006 (entitled "Professional development opportunities"), the Institute, in synergy with other research institutions, activated selection procedures for career advancements, in pursuance of Article 15 of CCNL 7/4/2006, that had been frozen for ten years.

This is an important choice, because Article 15, in the current circumstances, is a useful career development tool for researchers and technologists for whom there were few career advancement opportunities in the past. As is well known, career advancements for research staff was harnessed by the government policies of previous years because priority had been given to turnover mechanisms, repeatedly freezing recruitment, and to the corrective actions ensuing from the introduction of the stability norms in the financial policy.

Furthermore, a program has been created that takes into account all the contractual and regulatory instruments in force, with particular reference also to the innovations introduced on the subject by Article 22 (15) of Legislative Decree 75/2017, i.e., the possibility of envisaging

internal selection procedures for the career progression of permanent staff, without prejudice to the possession of the necessary qualifications required for access from the outside.

The number of posts for these reserved selective procedures has been set at 30, as per Resolution no. 6 attached to Minutes no. 40 of the Board of Directors of 18 June 2020, transposing Resolution 1-d of 27 March 2019.

The procedures adopted to implement the 2018 recruitment plan are reported in Table 7.

Table 7. 2018 Recruitment plan of the ISS

Qualification	Level	Paragraph 1	Paragraph 2	Article 5	Article 22	Recruitments
Research Director / Technology Director	I	3		30		2
Senior Researcher / Senior Technologist	II	10		70		3
Researcher/Technologist	III	30	10		20	5
Administrative Officer	IV	2			5	
CTER	V	11	7		5	
CAER	VII		3			
OPTER	VI	2				
Total		58	20	100	30	10

CTER (Collaboratore Tecnico Enti di Ricerca): Technical support staff of Research Institutions
 CAER (Collaboratore di Amministrazione): Administrative support staff of Research Institutions
 OPTER (Operatore Tecnico): Technical Operator of Research Institutions

For the sake of completeness, it is worth recalling that the previous plan also included selective procedures for economic raises and career progressions respectively for 172 persons in pursuance of Article 53 of the 1998 CCNL and for 291 persons in pursuance of Article 54 of the 1998 CCNL.

In order to continue pursuing the objective of encouraging the development of research careers, in 2020 a procedure reserved for permanent employees was launched through announcements for mobility between equal profiles (Articles no. 52 and 65 CCNL 21.2.2002 as amended).

6.2 • Recruitment needs (2021-2023)

This recruitment plan is designed to return to an ordinary recruiting process, also in light of the renewed regulatory context, after a phase characterized by the stabilization norms that had to be complied with in the previous plan.

The context of reference of the recruitment plan is delimited by the following norms:

- Legislative Decree 218/2016, which, with the provisions set out in Article 9, replaced the previous turnover measure, and introduced the 80% limit for recruitment by public research bodies;

- changes to the 2018 Institute’s ROF;
- “Guidelines for drafting recruitment plans in the Public Administration” issued by the Minister for Simplification and Public Administration and by the Civil Service Department, of 8 May 2018.

Table 8 shows the number of staff in the 2018-2020 three-year period

Table 8. ISS staff in the 2018-2020 three-year period

Profile	Level	31.12.2018	31.12.2019	31.12.2020
Executive Director Level 1	I	2	2	2
Executive Director Level 2	II	8	8	8
Total		10	10	10
Research Director	I	48	42	32
Senior Researcher	II	198	188	169
Researcher	III	509	530	528
Total		755	760	729
Technology Director	I	7	8	6
Senior Technologist	II	19	22	21
Technologist	III	42	47	45
Total		68	77	72
Administrative Officer	IV	44	41	41
Administrative Officer	V	8	12	19
Total		52	53	60
CTER	IV	251	237	212
CTER	V	174	173	169
CTER	VI	192	205	217
Total		617	615	598
CAER	V	95	90	76
CAER	VI	38	38	33
CAER	VII	27	27	33
Total		160	155	142
OPTER	VI	66	58	45
OPTER	VII	56	56	50
OPTER	VIII	88	88	97
Total		210	202	192
Total Permanent Staff		1872	1872	1803

Tables 9 and 10 show the turnover of statutory personnel in 2019 and 2020.

For sake of completeness, the turnover of statutory personnel is shown for the 2019-2020 period (Table 11).

Table 9. Turnover of statutory staff in 2019

Profile	Lev.	In post as at 31.12.2018	Recruitments 2019*	Retirements 2019	In post as at 31.12.2019	Difference
Research Director	I	48	1	7	42	-6
Senior Researcher	II	198	3	13	188	-10
Researcher	III	509	29	8	530	21
Technology Director	I	7	1		8	1
Senior Technologist	II	19	3		22	3
Technologist	III	42	6	1	47	5
CTER	IV	251		14	237	-14
CTER	V	174		1	173	-1
CTER	VI	192	14		205	13
OPTER	VI	66		8	58	-8
OPTER	VII	56			56	0
OPTER	VIII	88	3	3	88	0
Central Director	I	2			2	0
Executive director	II	8			8	0
General Director						
Director Article 15 septies Leg. Decree 502/92						
Administrative Officer	IV	44		3	41	-3
Administrative Officer	V	8	4		12	4
CAER	V	95		5	90	-5
CAER	VI	38		1	38	0
CAER	VII	27			27	0
Total		1872	64	64	1872	0

* Human resources were hired under the 2018 recruitment plan and in compliance with Law 68/1999.

Lev. Level

Table 10. Turnover of statutory staff in 2020

Profile	Lev.	Situation as at 31.12.2019	Recruitment 2020*	Retirements 2020	Upgrades		Balance as at 31.12.2020	Diff.
					from	to		
Research Director	I	42		10			32	-10
Senior Researcher	II	188		19			169	-19
Researcher	III	530		3		1	528	-2
Technology Director	I	8		2			6	-2
Senior Technologist	II	22		1			21	-1
Technologist	III	47		1	1		45	-2
CTER	IV	237		22	3		212	-25
CTER	V	173		3	2	1	169	-4
CTER	VI	205	2			10	217	12
OPTER	VI	58		7	6		45	-13
OPTER	VII	56			6		50	-6
OPTER	VIII	88	10	1			97	9
Central Director	I	2					2	
Executive Director	II	8					8	
General Director								
Director Article 15 septies Leg. Decree 502/92								
Administrative Officer	IV	41		3		3	41	
Administrative Officer	V	12				7	19	7
CAER	V	90		8	6		76	-14
CAER	VI	38		1	5	1	33	-5
CAER	VII	27				6	33	6
Total		1872	12	81	29	29	1803	-69

* Human resources were hired under the 2018 recruitment plan and in compliance with Law 68/1999.

Lev: Level

Diff: Difference

Table 11. Turnover of temporary staff in 2019 and 2020

Profile	In post as at 31.12.2018	Recruitments 2019	Retirements 2019	In post as at 31.12.2019	Difference
Research Director	5	1	1	5	0
Senior Researcher	2		2	0	0
Researcher	91	19	28	82	-9
Technology Director	3		1	2	-1
Senior Technologist	5		3	2	-3
Technologist	13	1	6	8	-5
CTER	32	6	15	23	-9
OPTER	2	3	2	3	1
Administrative Officer	3		2	1	-2
General Director *	3			3	0
Director** Article 15 septies Leg. Decree 502/92	11		2	9	-2
Total	170	30	62	138	-30
	As at 31.12.2019	2020	2020	As at 31.12.2020	
Research Director	5			5	
Senior Researcher					
Researcher	82		2	80	-2
Technology Director	2			2	
Senior Technologist	2			2	
Technologist	8		1	7	-1
CTER	23			23	
OPTER	3			3	
				1	
General Director *	3			3	
Director** Article 15 septies Leg. Decree 502/92	9		3	6	-3
Total	138	0	6	132	-6

* Director General ISS, Director CNT and Director CNS

** Staff recruited by CNT and CNS (as per Article 19 bis, (5) of the ROF)

6.2.1 • Elements of the analysis: qualitative parameters

The analysis of recruitment needs made on the basis of qualitative parameters determines the professional profiles and professional skills required in the sectors that are most affected by the evolutionary processes under way, achieving the dual objective of ensuring continuity and strengthening the new sectors.

It should be noted that this PTA was drawn up taking into account the needs associated with the breakdown of activities of the Institute into 7 macro-areas (Box 3), which include institutional

activities, scientific research and training, information and dissemination (third mission), in accordance with the organizational autonomy attributed to the Institute by Legislative Decree 218/2016, and in compliance with the policy document of the Minister of Health of 26 September 2017.

Box 3. Macro-areas of the activities of ISS

1. Health and environment
2. Drugs
3. Communicable diseases
4. Non-communicable diseases and rare diseases
5. Disease prevention, health promotion and global health
6. Food safety and nutrition
7. Chemistry, radiations, innovative technologies and telemedicine

The analysis of recruitment needs was then matched with the seven macro-areas of activities of the Institute, and harmonized with the five general objectives laid down in the management plan set out in this PTA (Figure 7).

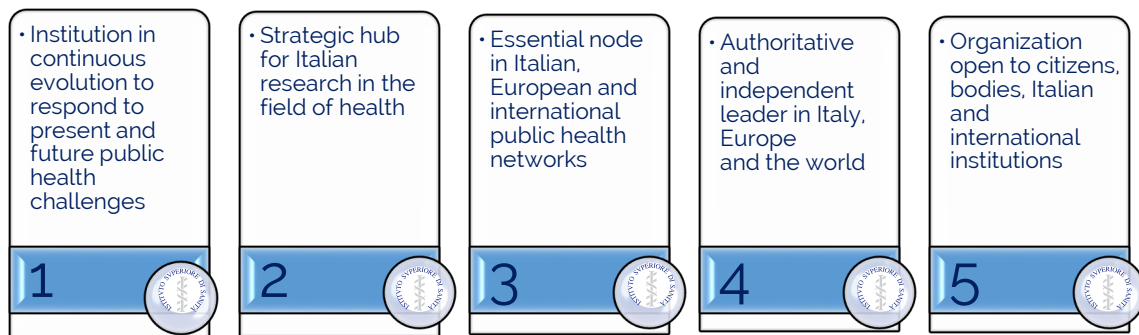


Figure 7. General objectives of the Institute

In particular, once the strategies that will guide the activities of the Institute in the next three years are defined, a recruitment plan will be drawn up articulated according to different procedures aimed at:

- a. recovering the skills lost over the years (or in the process of being lost) to ensure that the activities assigned to the Institute are performed;
- b. acquiring new professionals, possessing specific skills currently not available in the Institute and which will enable the Institute to keep up with the innovation and technical-scientific evolution in the health sector;
- c. strengthening the administrative technical structure called upon to play a supporting role in the technical-scientific system and to develop increasingly specific skills, in accordance with a technological matrix that is to redefine the traditional role of the administration (in particular to meet the need for qualified professionals for the IT Office, the Logistics, Projects and Maintenance Office and the Management Planning and Control Service);
- d. using tools for enhancing the existing professional staff, avoiding the creation of temporary posts and at the same time not wasting in-house valuable resources by using the instruments

contained in Article 20 of the Madia Law and Article 12 bis of Legislative Decree 218/2016, the so-called “tenure track”.

6.2.2 • Elements of the analysis: quantitative parameter

The quantitative parameter, on the other hand, includes a predictive analysis of the exit of pensionable staff in the three-year period considered, relating it to the more traditional and consolidated sectors of the Institute’s mission (also by mapping the skills present in the Institute and the new skills required by the various Structures).

6.2.3 • Exit of pensionable staff – trend in the 2021-2023 three-year period

The representation provided below confirms the downward trend in the number of staff in active service caused by the strong increase in the exit of pensionable staff, which occurred during the last two years, and by the so-called “*Quota 100*” regulatory measure which induced many people to retire (Figures 8 and 9).

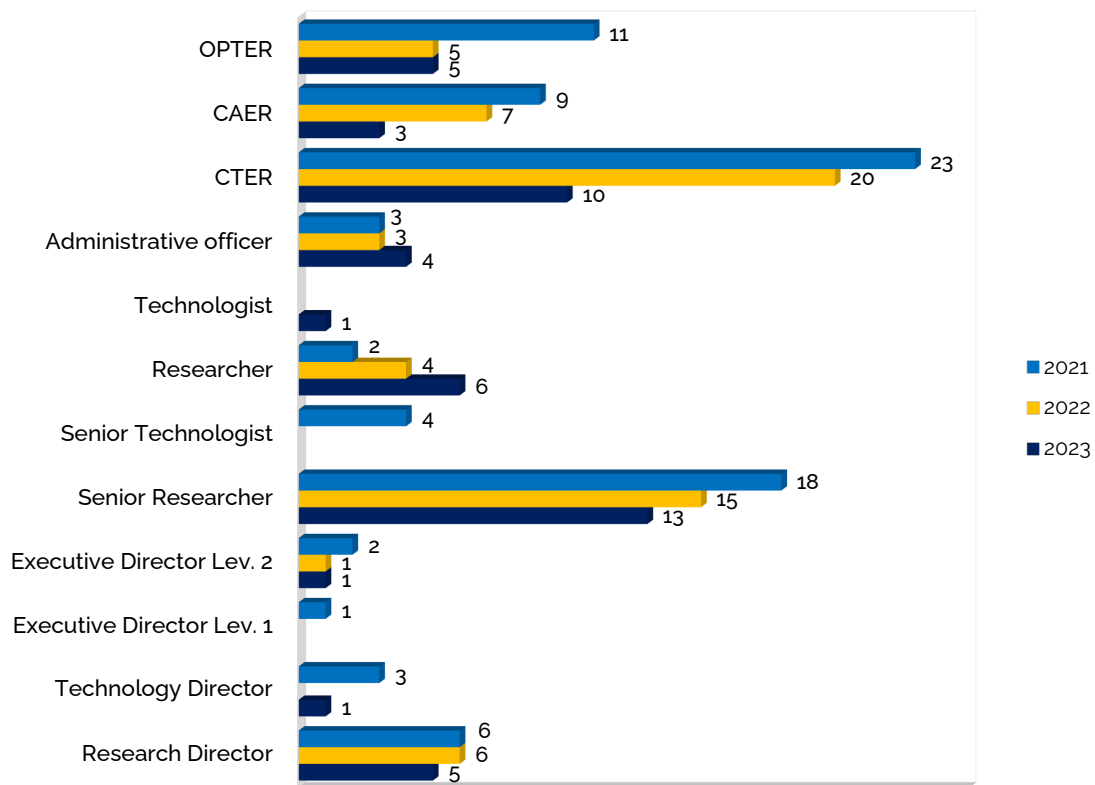


Figure 8. Retirement of ISS staff by profile (2021-2023)

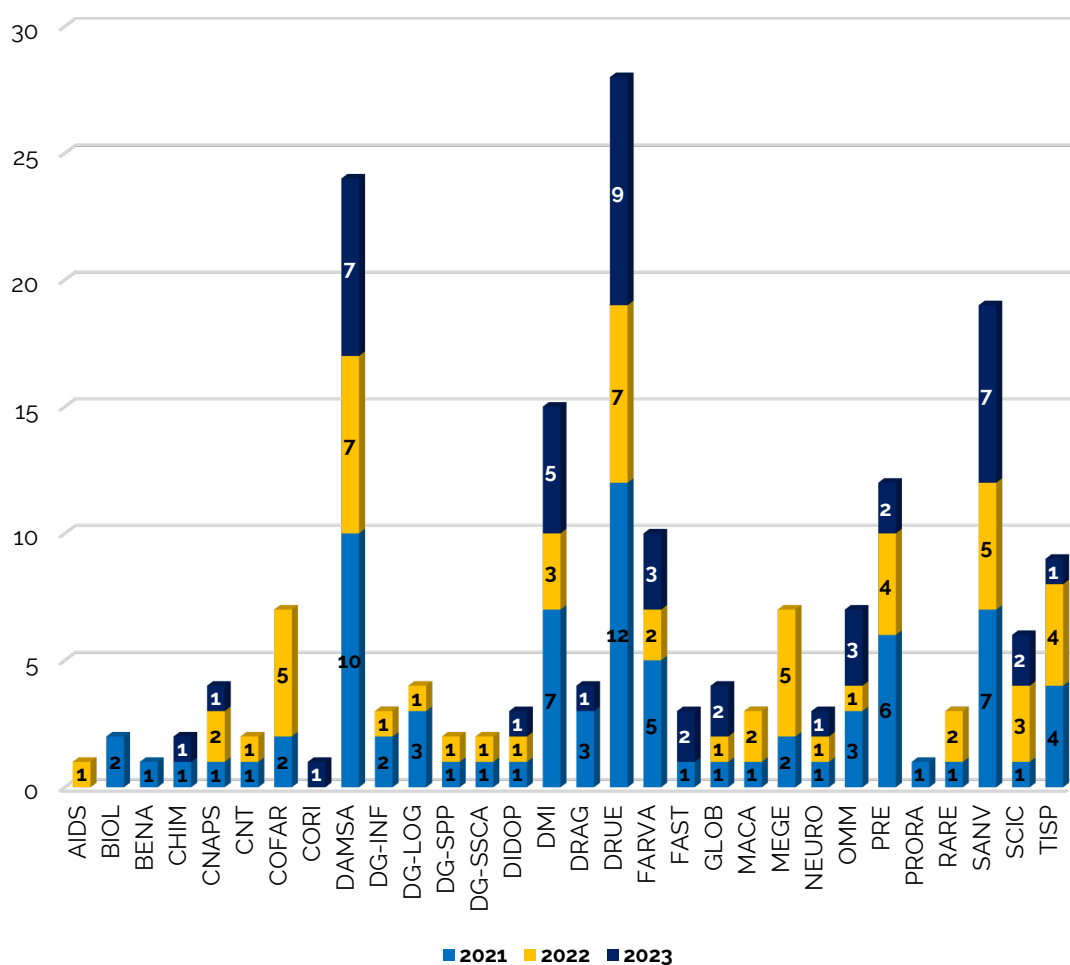


Figure 9. Retirement of ISS staff by Structure (2021-2023)

There appears to be a considerable decrease in the number of staff working in the research area (Senior Researcher) and in the executive positions of the technical-administrative area. This is confirmed in Figure 9, which offers a summary of the exit of pensionable staff in the three-year period being considered here.

The high number of employees retiring is confirmed also for the year 2021, as a consequence – among other things – of the favourable regulatory measures.

This trend should slow down in the next few years because the current rules on retirement will soon lose their efficacy having been adopted for only a short period of time.

It is worth pointing out that a significant number of researchers with specific skills will soon be retiring, given their age, and if they are not promptly replaced, the on-going research activities will be negatively affected. For this reason, new resources will have to be hired progressively during the next three years.

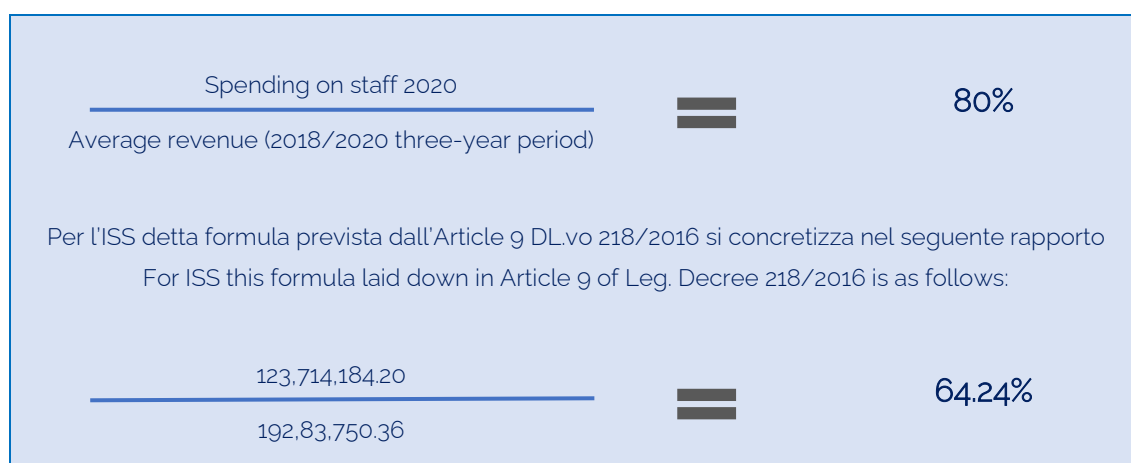
6.3 • Global analysis of economic resources

By stating the “special” nature of research institutions, Legislative Decree 218/2016 recognizes their autonomy in various areas, including recruitment.

In this perspective, the only limit considered in the phase of drawing up the recruitment plan is placed by the legislation of reference that sets the budget limit of 80% of expenditure to be used for recruitment, in other words for the future personnel of the Institute.

The parameters set forth in the provisions of Article 9 of Legislative Decree 218/2016 define the hiring capacity of the Institute for the year 2021 (Box 4).

Box 4. Requirements for recruitment*



* data from the 2020 Annual Accounts compares Tables A, B and C in the Appendix to the Recruitment Plan.

6.4 • Instruments for implementing the recruitment plan

Having reconstructed the guidelines of the qualitative and quantitative analysis of staff needs, the recruitment plan is then defined taking into account the general and special objectives laid out in the Three-Year Activity Plan for the 2021-2023 period.

In fact, an analysis was made of the exit of pensionable staff together with a careful survey of the new staff required to fulfil the five objectives that constitute the strategic policy of the Institute.

Particular emphasis was placed on the renewal of the technical-scientific Structure required in order to carry out the missions entrusted to the Institute.

The overall outcome of the reference indicators is shown in Table 12.

The cost of this recruitment plan amounts to approximately € 8,500,000.00.

Table 12. Human resources and recruitment plan for the 2021-2023 period

Profile	Statutory staff on duty as at 31.12.2020	Recruitment plan		
		2021*	2022	2023
Executive Director Level 1	2	1		
Executive Director Level 2	8	3	1	1
Research Director	32	8	7	8
Senior Researcher	169	20	20	15
Researcher	528	58	36	30
Technology Director	6	4	1	1
Senior Technologist	21	4	3	3
Technologist	45	17	9	9
Administrative Officer	60	5		
CAER	142			
CTER	598	26	30	35
OPTER	192	2		
Total	1803	148	107	102

* A share of the measure is for Institutes as per Article 12 bis Leg. Decree 218/2016 and Article 20 (1) Leg. Decree 75/2017. Compare Tables D and E in the Appendix to the Recruitment Plan

6.4.1 • Recruitment procedures and contracts

A plan was drawn up of recruitment needs, broken down into two segments:

1. recruitment aimed at recovering the skills lost over the years and at the acquisition of new professional skills required by the evolution of the Institute's Structures – following the changes made in the Internal Rules of Procedure of the Institute. The Recruitment Plan is designed in such a way as to respond to the dynamic nature of the ISS as a research institution at the service of the Country that needs to adapt to the incessantly increasing needs of ever-changing technologies and innovations in the field of research;
2. announce a call – with a view to the acquisition of specific figures – to recruit, through “mobility”, the professionals having the skills required for the National Transplant Centre and the National Blood Centre.

Consequently, “recruitment” for 2021 will follow two paths:

1. *Organizing procedures for competitions open to outside participants* (definable as ordinary recruitment), that can be held – under the provisions of Article 35 of Legislative Decree 165/2001 – through selective procedures to ascertain the required professional skills ensuring that access is given to applicant from outside the Institute. In this connection, the general norms of reference are contained mainly in the aforementioned Article 35, in Presidential Decree no. 487 of 9 May 1994, in Presidential Decree no. 272 of 24 September 2004, and in Presidential Decree no. 70 of 16 April 2013. Besides these general provisions there are also those relating to the specific categories of personnel of the Institute, including Articles 5, 8, 11, 12, 13, 14, 15, 16, 17, 18, 20, 23 of the “Regulations for the recruitment of the staff of the Istituto Superiore di Sanità” (Decree of the President of ISS, 3.10.2002).

To this end, public competitions will be held for:

- 7 posts for personnel having the profile of Director of Research to be recruited through a national public competition based on qualifications only [for a cost of € 559,173.07];
- 16 posts for personnel with the profile of Senior Researcher through a national public competition based on qualifications and exams (interview) [for a cost of € 1,001,795.20];
- 14 posts for personnel with the profile of Researcher through a national public competition based on qualifications and exams (written test and interview) [for a cost of € 700,682.36];
- 2 posts for personnel with the profile of Director of Technology through a national public competition based on qualifications and exams (interview) [for a cost of € 159,763.73];
- 4 posts for personnel with the profile of Senior Technologist through a national public competition based on qualifications and exams (interview) [for a cost of € 250,448.80];
- 14 posts for personnel with the profile of Technologist through a national public competition based on qualifications and exams (written test and interview) [for a cost of € 718,253.34];
- 21 posts for staff with the CTER profile through a national public competition based on qualifications and exams (written test, theoretical and hands-on test and interview) [for a cost of € 1,107,406.86];
- 3 posts for directors with the profile of Level 2 Administrative Director [for a cost of € 217,317.00].

The procedure for covering the position of Level 1 Administrative Director will also be initiated.

2. *Enhancement of the professional resources present in the Institute, according to the rules provided for by current legislation:*

- a) pursuant to Article 20 (1) of Legislative Decree 75/2017, two posts for Director of Technology [for a cost of € 159,763.73], six posts for Researchers [for a cost of € 300,292.44], five CTER posts [for a cost of € 263,668.30], one post for Administrative Officer [for a cost of € 53,885.69] and two OPTER posts [for a cost of € 85,262.04] provided that candidates are in possession of the requirements prescribed by the norm, or that the candidates:
 - o joined the ISS, after 28 August 2015, with fixed-term contracts and is now hired by the ISS;
 - o were hired on a fixed-term basis, for the same activities, through a competition (even if for a different Public Administration);
 - o were employed by the ISS, as at 31 December 2017, for at least three years in the last eight years, even if on an off-on basis.
- b) pursuant to Article 12 bis of Legislative Decree 218/2016, two posts with the profile of Senior Researcher [for a cost of € 125,224.40], thirty-six posts with the profile of Researcher [for a cost of € 1,801,754.64], three posts with the profile of Technologist [for a cost of € 153,911.43]. For all of these posts it will be possible to transform fixed-

term contracts into permanent employment relationships provided that the fixed-term contracts were for the performance of research and technological activities. Candidates will be selected on the basis of qualifications and an interview, provided that they have worked in that position for 3 years in the past 5 years, even if on an off-and-on basis. For this activity 50% of the recruitment resources allocated by the PTA for posts of the same level, will be made available.

Procedures for voluntary “mobility” will be activated for up to a maximum of 9 posts out of the positions provided for in this Plan, in accordance with the provisions of Article 30 of Legislative Decree 165/2001: the procedure provides for the issuance of a Call, exclusively addressed to employees of public administrations. The candidates need to fill in the application form requesting to be considered for the available posts at the Istituto Superiore di Sanità. Obviously, candidates need to be granted authorization by Administration that employs them, since under Civil Law this procedure is equivalent to a contract release.

Having completed the description of the Recruitment Plan for the three-year period being examined here, further elements of the human resources cycle are illustrated in the following.

6.4.2 • Enhancing and valorising the skills of the Institute's human resources and career advancements

In 2021, the mapping and updating skills will continue, by creating a “skills bank”. The project, drawn up with the contribution of the Directors of the technical-scientific Structures, defines the methodological skills and the ability to deliver services, consultancy and training.

Another strategic line of the Institute's personnel policy is to encourage careers by implementing the advancement mechanisms envisaged in the Collective Agreements.

In the three-year period of reference, the enhancement procedures will be renewed, where possible, to reshape the current staffing structure of the Institute.

Similarly, in the 2021-2023 period, new negotiations will also be undertaken with the Trade Unions to update the bargaining discussions concerning the application of the contract conditions for level advancements for the fourth and eighth profiles (Articles 53 and 54) (the personnel to be enhanced must also include temporary staff) and for economic progressions, in accordance with the following outline.

Economic advancement under Article 53 CCNL of 21 February 2002

The posts that are available concern the following profiles:

- Administrative Officer
- Technical Support Staff for Research Bodies
- Administration Partner of Research Institutions
- Technical Operator of Research Institutes

Upgrades under Article 54 CCNL of 21 February 2002 for eligible staff as at 01/01/2021

The posts that are available concern the following profiles:

- Administrative Officer
- Technical Support Staff for Research Bodies

- Administration Support staff of Research Institutions
- Technical Operator of Research Institutes

Incentives

In 2020 the ISS had already earmarked funds for staff incentives and initiated discussions with the Unions for identifying the instruments to be used, in compliance with the legislation of reference for first and second level posts. Subject to agreement with the Trade Unions, *ad hoc* resources will be allocated also for the 2022 and 2023 two-year period from the accessory fund in order to consolidate the positive approach that was started in the previous management cycle.

Training of internal staff

The previous 2018-2020 recruitment plan (and relative update) had envisaged the adoption of Procedural Guidelines for the training of ISS internal staff which were approved by the Board of Directors on 17 December 2019 with relevant decree being issued by the President on 28 January 2020. According to the provisions of the “Procedural Guidelines on the training of employees of the Istituto Superiore di Sanità” indicated above, starting from 2020 the proposal for the personnel training program is formulated by identifying *ad hoc* training courses (for general and / or specific training) tailored to the specific professional profiles that are required for the updating and improvement of the skills of the different professional profiles of the Institute, so that all staff can effectively contribute to achieving its objectives, and, in compliance with the current performance system of the Institute the staff can contribute to achieving the expected results. What is described in the Procedural Guideline applies not only to the personnel of the technical-administrative Structures, but also to the personnel of the Departments, the Centres and the Technical-Scientific services.

It should be noted that, in order to upgrade the qualifications of its internal staff, the ISS designs, manages and monitors the training initiatives identified as strategic for the technical, administrative and research personnel, providing adequate tools for information, updating and professional growth, in compliance with the criteria of fairness and equal opportunities.

Over the next three years, the ISS is committed to promoting new ways of providing training (e-learning and distance learning) and to enhancing the professionalism of its internal staff, also by referring to the organizational systems of other similar institutes as benchmarks.

In line with the 2021 Performance Plan, in fact, the Administration has set itself the goal of increasing the specific training of ISS staff for the development of the Institution’s skills and the career progression of its researchers. In order to ensure that training needs of internal staff are met, a specific training plan will be drawn up aimed at enhancing the skills of the professional figures that already work for the Institute (Box 5).

Differentiated training courses and initiatives will be defined, in terms of content and levels of detail, in relation to the different roles of employees. A map of needs will be drawn up, involving the Technical-Scientific and administrative structures on the basis of the objectives identified in the PTA and the training needs defined in the POLA (Operational Plan for Smart Working). The annual plans will accurately illustrate the contents, timing, recipients and resources required to deliver training courses in the 2021-2023 three-year period.

In addition, an integrated IT system will be created that will allow to manage and assess skills within the ISS, producing a wealth of useful information for defining staff requirements, the

professional figures and essential skills required so as to adequately define the staff training process. A trial run will be made of the pilot project for the profiling and computerized processing of applications for participation in internal selections. The project will subsequently be extended to public competitions as well (for this purpose the CNR SIGLA platform will be used).

Box 5. Thematic areas of training for the staff of ISS

- Safety in the workplace and in smart working settings
- Data protection and security on site and in smart working settings
- Fight against corruption, with a focus on ethics and legality
- Equal opportunities, a culture of respect for people and prevention of sexual harassment in the workplace (CCNL 2002-2005, Directive of 23 May 2007 on "Measures implementing equality and equal opportunities between men and women in Public Administrations")
- Administrative and managerial issues of particular importance: training of the administrative technical staff, including the staff dedicated to administrative activities operating in the Technical-Scientific Structures; new administrative and accounting procedures deriving from the adoption of the new IT procedure
- Subjects concerning the research areas
- Training courses for the acquisition of managerial skills for digital transformation
- "ISS for ISS" webinars to share internal skills
- Webinars with the directors of the structures and the staff for promoting a Performance-based culture
- Continuous training and refresher courses also for people with disabilities

Initiatives addressed to young researchers: human capital as a strategic lever for renewal

The difficulties in gaining access to the labour market for young researchers are well known and their careers, which are fraught with difficulties and obstacles, are frequently interrupted because of the protracted conditions of contractual and economic instability.

Being aware of the decisive value of human resources, the ISS has prepared a series of actions which include:

1. support for young researchers (including researchers from abroad);
2. relations with specialization schools;
3. relations with educational institutes that run PhD programs.

The Institute intends to focus on the new generations, by promoting initiatives aimed at conferring hospitality and scholarships for young researchers, who, under the supervision of an internal Tutor, will be able to enrich the current reality of the Institute and, at the same time, become attractive resources for organizations and companies in the health sector. New provisions have been defined to identify training courses for the management and assignment of scholarships and research PhDs, according to detailed guidelines.

The ISS is ready to welcome individuals with advanced technical and scientific skills adequate for the standards of a research and training institute that is constantly in contact with the national and international scientific community. Working for the ISS requires commitment, dedication and high levels of competence and of performance in line with its objectives, and, in return it offers the privilege of belonging to a central institution that works to improve knowledge and progress in public health.

Retirement

Some regulatory provisions, whose essential features are described below, apply to some of the staff of the Institute who, in pursuance of such provisions, will be able to retire in advance with respect to the provisions of the general rules. Also for this aspect the Institute will have to periodically review its staff needs:

1. “*Quota 100*” measure (62 + 38)
early retirement upon fulfilling a double condition: 62 years of age and 38 years of paid contributions. The effective date of payment of the pension is deferred by 6 months and a minimum notice of 6 months is required for public employees. This opportunity is reserved for those who fulfil both conditions by 31/12/2021, with the possibility of retiring even after that date;
2. The “*Opzione donna*” (Special Measure for Women)
envisaged for female workers who by 31/12/2020 fulfil the double condition of 58 years of age and 35 years of paid contributions, with a mandatory option for the contribution-based calculation system. The starting date of the pension is deferred by one year from the fulfilment of the two conditions.
3. Early retirement (wage-based and mixed system)
Early retirement for men upon completing payment of contributions for 42 years plus 10 months, and for women upon completing payment of contributions for 41 years plus 10 months, regardless of age. In both cases, the date from which the pensions will be paid is deferred by 3 months from final payment of the contributions. This opportunity is reserved for employees who meet these requirements by 31 December 2026.

In addition to the retirement of employees upon reaching pensionable age, there are also employees who, although being in the organization chart of the Institute, are seconded to other institutions within the framework of the customary cooperation among public bodies. The employees seconded to other public bodies are 22 (Table 13).

Table 13. ISS employees seconded to other administrations

Body/Institution	Unità in comando	Seconded staff
Ministry of Health	8	7
Lazio Region	1	
ASL Roma E	1	
AIFA	3	
University of Bari		1
University of Udine		1

Appendix to the Recruitment Plan

Table A

Disaggregated audited revenues for the 2018-2020 three-year period	
Financial year	Revenues in €
2018	179,581,736.23
2019	178,099,051.11
2020	220,070,463.74

Table B

Annual revenues as reported in the Annual Report		
Financial year	Revenues in €	
2018	179,581,736.23	
2019	178,099,051.11	
2020	220,070,463.74	
TOTAL	577,751,251.08	
AVERAGE FOR THE THREE-YEAR PERIOD	192,583,750,36	
Staff expenditure 2020	123,714,184.20	
STAFF EXPENDITURE 2020	123,714,184.20	64.24%
AVERAGE REVENUE FOR THE 2018-2020 PERIOD	192,583,750,36	

Table C

Annual revenues as reported in the Annual Accounts		
Financial year	Revenues in €	
2018	179,581,736.23	
2019	178,099,051.11	
2020	220,070,463.74	
TOTAL	577,751,251.08	
AVERAGE FOR THE THREE-YEAR PERIOD	192,583,750,36	
Staff expenditure 2020	123,714,184.20	
STAFF EXPENDITURE 2020 + COST OF RECRUITMENT PLAN 2021 (8,500,000)	132,124,184.20	68.65%
AVERAGE INCOME FOR 2018-2020	192,583,750,36	

Table D

2021 Human Resources and Recruitment Plan (with indication of cost)			
Profile	Statutory staff on duty as at 31.12.2020	Recruitment Plan 2021*	Cost in €
Executive Director Level 1	2	1	142.558,00
Executive Director Level 2	8	3	217.317,00
Research Director	32	8	659.823,92
Senior Researcher	169	20	1.300.126,40
Researcher	528	58	3.033.196,42
Technology Director	6	4	329.911,96
Senior Technologist	21	4	260.025,28
Technologist	45	17	889.040,33
Administrative Officer	60	5	275.062,45
CAER	142		
CTER	598	26	1.311.960,00
OPTER	192	2	87.117,36
Total	1803	148	8.506.139,12

* A share of the measure is for Institutes as per Article 12 bis Leg. Decree 218/2016 and Article 20 (1) Leg. Decree 75/2017.

Table E

Unit cost per profile		
Profile	Totale cost in €*	Amount paid by ISS
Executive Director Level 1	142.558,00	54.713,76
Executive Director Level 2	72.439,00	27.802,09
Research / Technology Director	82.477,99	31.655,05
Senior Researcher / Technologist	65.006,32	24.949,43
Researcher / Technologist	52.296,49	20.071,39
Administrative Officer	55.012,49	21.113,79
CTER	50.460,00	19.366,55
OPTER	43.558,68	16.717,82

* The unit cost of each profile includes salary increases as per CCNL 2016-2018 (Section on Universities and Research)

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