



European
Partnership
for Pandemic
Preparedness

COUNTRY PROFILE *Italy*

The competences for health are regionalised in Italy with national governance for national health emergencies such as pandemic response.

The Ministry of Health aims to protect the constitutional right to health, and exercises the following functions pertaining to the State: protection of human health, coordination of the national health system, Veterinary Health, Health protection in the workplace and Food hygiene and safety. The National Institute of Health (Istituto Superiore di Sanità – ISS) is the main centre for research, control and technical-scientific advice on public health in Italy. In this role, it provides technical and scientific support to the Italian Ministry of Health and to the National Health System. The National Institute of Health is also instrumental implementing national disease surveillance systems, including epidemic intelligence, and coordinating networks of reference laboratories to collect key data timely and perform in depth statistical, modelling, microbiological and genomic analyses and risk assessments to inform public health action.

The regions set up crisis management units with regional health authorities, directors of local health units and the prefectures as representatives of the central state. In the early response, the government also activated the Department of Civil Protection to support regions in the procurement of pharmaceuticals, medical devices, human resources and infrastructure. (from State of Health in the EU Italy Country Health Profile 2021¹). The latest pandemic plan was published in 2021⁽²⁾ and is currently in the process of being updated in line with WHO guidelines. During the COVID-19 pandemic, Italy's emergency response was led by the Prime Minister's Office, supported by the national Department of Civil Protection and the "Extraordinary Commissioner" appointed in March 2020 to coordinate measures to combat the pandemic. Binding decisions were issued via Prime Ministerial decrees, although these increasingly reflected consultation and mediation with regional leaders, particularly with regard to imposing lockdowns and other restrictions under the state of emergency activated in March 2020. A Scientific and Technical Committee was established in February 2020 to provide technical support and scientific evidence for the central government's decision-making on preventive and protective measures.

Concerning antimicrobial resistance (AMR), The PNCAR 2022–2025³ is Italy's strategic framework to combat antimicrobial resistance (AMR). Approved by the State-Regions Conference on 30 November 2022, it builds upon the previous 2017–2020 plan and emphasises a One Health approach, integrating human, animal, and environmental health sectors. It ensures effective governance and coordination among national and regional authorities. The 2024–2028 National Influenza Pandemic Plan, focused on the prevention, will be able to implement concrete measures such as: strengthening the Departments of Prevention, expanding the network of microbiology and virology laboratories, boosting research, and defining the roles and responsibilities of all institutions within the National Health Service (SSN) and coordination networks for pandemic preparedness and response to respiratory-transmitted pathogens.⁴ Italy has also adopted the National Plan for the Prevention, Surveillance, and Response to Arboviral Diseases (PNA) 2020–2025, a strategic document aimed at preventing and controlling the spread of vector-borne diseases such as Dengue, Chikungunya, Zika, West Nile Virus, and Toscana Virus — all transmitted by vectors like mosquitoes and ticks. The main objectives are the coordination and monitoring of human, animal, and environmental health sectors. The Regional authorities must develop operational plans for prevention and response. The need for a rapid implementation of control measures in the event of outbreaks and Public awareness and education on risks and preventive measures are highlighted.

In case of outbreak the institutional agencies Italian Ministry of Health (It-MoH), Ministry of University & Research (MUR), National Research Council (CNR) and the National Institute of Health (ISS), are mobilized to support R&I. Presidency of the Council of Ministers plays a central coordinating role in activities related to the prevention and management of pandemic risk, due to its position as the guarantor of the unity of political and administrative direction. This is ensured by promoting and coordinating the activities of the ministers, as established in Article 95 of the Constitution. The Civil Protection Department's role is ensuring that the public is well-informed about potential risks and the appropriate actions to take, as well as the plans in place to manage such risks (Legislative Decree No. 1/2018)⁵

¹ https://health.ec.europa.eu/system/files/2021-12/2021_chp_it_english.pdf

² <https://www.salute.gov.it/new/it/tema/influenza/piano-pandemico-influenzale-2021-2023/>

³ https://www.salute.gov.it/imgs/C_17_pubblicazioni_3294_allegato.pdf

⁴ <https://www.salute.gov.it/new/it/tema/influenza/>

⁵ <https://www.protezionecivile.gov.it/it/normativa/decreto-legislativo-n-1-del-2-gennaio-2018--codice-della-protezione-civile/>

R&I Policies and Strategies *The information is not exhaustive and should be updated regularly.*

Country has a dedicated strategy for R&I related to pandemic threat? Yes

Italy has established a dedicated strategy for research and innovation (R&I) related to pandemic threats, primarily through its National Recovery and Resilience Plan (PNRR), which is part of the European Union's NextGenerationEU initiative. The PNRR outlines significant investments aimed at enhancing the country's preparedness and response to health crises. Of particular relevance to pandemic preparedness is the One Health Basic and Translational Actions Addressing Unmet Needs on Emerging Infectious Diseases -INF-ACT- project ⁽⁶⁾ that addresses pressing unmet needs of human emerging infectious diseases in both fundamental as well as in translational aspects, with a One Health approach focusing on: emerging and re-emerging viral diseases (with a focus on respiratory viruses and zoonotic viruses); arthropod vectors and vector-borne pathogens (with a focus on VBDs most at risk of expand or emerge in Italy, such as arboviruses); and diseases sustained by bacteria and fungi resistant to multiple antibiotics (AMR, with a focus on the molecular mechanisms of MDR).

R&I strategy URL: https://commission.europa.eu/business-economy-euro/economic-recovery/recovery-and-resilience-facility/country-pages/italys-recovery-and-resilience-plan_en

From the CNR, the <https://dsb.cnr.it/pandemics/home-en.html>

Country has an open science portal with information on publicly financed scientific research? Yes

R&I portal <https://open-science.it/> and <https://open-science.it/english>

Several research institutions have published portals on open science; some examples are : CNR : <https://publications.cnr.it/> ; PublISS (<https://publ.iss.it>); Open Science Tuscany <https://www.toscanaopenresearch.it/en/>;

Country has R&I webpage on: Several dedicated research and innovation (R&I) initiatives addressing pandemic threats, including COVID-19, antimicrobial resistance (AMR), arboviruses, and respiratory viruses.

Website open science/ open data initiative with respect to pandemic threats, such as COVID-19 open

Name & URL

[ResearchItaly portal](#) , managed by the Ministry of University and Research (MUR), the serves as a comprehensive platform highlighting Italy's research initiatives, including those related to health and pandemic preparedness.

URL: <https://researchitaly.mur.gov.it/en/homepage-en/>

ISS Portal, offers comprehensive information on its activities, including research projects, publications, and health initiatives. While it doesn't serve as a centralised hub exclusively for pandemic preparedness, it provides access to various resources and updates in this domain. URL: <https://www.iss.it/web/iss-en/>

EpiCentro is the ISS's dedicated platform for public health and epidemiology. It offers extensive resources on infectious diseases, surveillance data, and health promotion. During the COVID-19 pandemic, EpiCentro served as a central repository for guidelines, reports, and real-time data. URL: <https://www.epicentro.iss.it/en/coronavirus/sars-cov-2-integrated-surveillance-data>

The ISS One Health approach, recognising the interconnectedness of human, animal, and environmental health. This perspective is integral to their strategies for managing zoonotic diseases and preparing for future pandemics. <https://www.iss.it/en/one-health>

Other examples of Website open science/ open data initiative with respect to pandemic threats, such as COVID-19 open

From Tuscany region:

<https://www.regione.toscana.it/-/bandoricerca-covid-19-toscana> ;
<https://www.regione.toscana.it/-/bando-ricerca-covid-19-toscana-esiti-e-prospettive>;
https://www.ars.toscana.it/banche-dati/dati-sintesi-sintinfettive-malattie-infettive-in-toscana?provenienza=home_tasti&dettaglio=ric_geo_infettive&par_top_geografia=090&par_top_anno=2022&par_top_malattie=TOTALE

Risorse Dati su Covid-19 (A global, searchable index of data sources on the Italian Covid-19 situation): <https://dati-covid.italia.it/>. The lesson of COVID-19 pandemic: <https://dsb.cnr.it/pandemics/home-en.html>

Country has coordinating structures to link public health needs and research needs? Yes,

Coordinating structures for health needs and research are located at the Ministry of Health (MoH) and High Institute of Health (ISS) and Ministry of University & Research (MUR).

⁶ <https://www.inf-act.it/>

R&I Infrastructures, initiatives and clinical trials

The information is not exhaustive and should be updated regularly.

Country has the following research infrastructure for infectious diseases and outbreaks available, or under construction : BSL 3; BSL 4; Emergency intervention units; Clinical trial units; Other

Name	Infrastructure Type	Infrastructure	URL	Max Capacity	Available for	Open to
BSL2-3 facilities are located in several Hospitals/Universities	BSL2-3					
CNAP National Pandemic Center	BSL4		https://www.biotechnopolo.it/en/national-pandemic-center-cnap/		public	Yes
Facilities for BSL4 research related to pandemic threats located at the National Institute for Infectious Diseases Spallanzani (Rome), and at the Hospital Sacco (Milan)	BSL4					
Instruct-ITALIA Italian Infrastructure for Integrated Structural	COVID 19 - Computational Services		https://talos.cerm.unifi.it/instruct-it/news/58-computational			
Regional Healthcare System in Tuscany	Clinical Trial Units		https://www.regione.toscana.it/sst		public	Yes
Toscana Life Sciences Foundation	BSL3 (Research organisation/Bioincubator)		https://www.toscanalifesciences.org/en/		public	Yes

Country supporting the participation to the following relevant for infrastructures:

Italy participates in many European research infrastructures, especially in the biomedical and public health fields, including pandemic preparedness. Among these are:

ECRIN/ItaCRIN (European Clinical Research Infrastructure Network). ISS is the national scientific partner of ECRIN through its Italian node , Itacrin. Supports multinational clinical research by providing services in study planning, regulatory affairs, data management, and monitoring. <https://www.itacrin.it/>

EATRIS/ A_IATRIS (Italian Advanced Translational Research Infrastructure in Medicine) and is coordinated by the Istituto Superiore di Sanità (ISS) <https://www.aiatris.it/>

BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure). ISS coordinates Italy’s participation in BBMRI, a pan-European research infrastructure of biobanks and biomolecular resources. <https://www.bbmri.it/>

EURO-BIOIMAGING (advanced imaging). With Advanced Light Microscopy Italian Node: Comprises five imaging facilities located in Naples, Genoa, Padua, Florence, and Milan. Molecular Imaging Italian Node: A multi-sited node focused on biomedical imaging, offering expertise in the acquisition and analysis of “in vivo” images. Phase Contrast Imaging Flagship Node Trieste. Digital Imaging Multimodal Platform Neuromed (DIMP NEUROMED); <https://www.eurobioimaging.eu/who-we-are/member-states/italy-2/>

INFRAFRONTIER (animal disease models); The Italian node is established at the 'A. Buzzati-Traverso' campus in Monterotondo, near Rome, which also hosts the Italian Outstation of the European Molecular Biology Laboratory (EMBL). <https://www.infrafrontier.eu/partner/consiglio-nazionale-delle-ricerche-cnr/>

INSTRUCT (structural biology); The Italian node of Instruct-ERIC is CERM/CIRMMP, located at the University of Florence. <https://talos.cerm.unifi.it/instruct-it/pages/cerm-cirmmp>

ISBE (system biology): The Italian node, ISBE-IT, is a Joint Research Unit (JRU) comprising the Università degli Studi di Milano-Bicocca; CNR (Consiglio Nazionale delle Ricerche); University of Naples Federico II (UNINA) and the University of Campania (UniCampania). <https://en.unimib.it/research/research-infrastructures/european-infrastructures-esfri/isbe>

ERINHA (European Research Infrastructure on Highly Pathogenic Agents). ERINHA brings together leading European Bio-Safety Level 4 (BSL4) and complementary (e.g., BSL3) facilities, along with national research institutes, to address the challenges posed by highly infectious diseases. The **Istituto Nazionale per le Malattie Infettive Lazzaro Spallanzani** (INMI) in Rome is Italy's leading institute for infectious diseases and national reference. <https://inmi.it/>

Italian Network for Infectious Disease Research "It-Idrin": It includes six IRCCS with infectious disease departments: Ospedale Maggiore Policlinico in Milan, Policlinico San Matteo in Pavia, Policlinico San Martino in Genoa, Ospedale San Raffaele in Milan, Policlinico Gemelli in Rome, and Ospedale Sacro Cuore Don Calabria in Negrar (VR). The project, funded by the Ministry of Health and coordinated by the National Institute for Infectious Diseases (INMI) Lazzaro Spallanzani

CERIC-ERIC: CERIC is a European Research Infrastructure Consortium (ERIC) integrating and providing open access to some of the most advanced analytical facilities in Europe to help science and industry. The project "Pathogen Readiness Platform for CERIC-ERIC Upgrade" (PRP@CERIC) aims to strengthen the CERIC-ERIC Research Infrastructure through the implementation of a geographically distributed and scientifically integrated digital ecosystem, offering academic, industrial and public health interconnected expertise and tools to address emerging human, animal and plant pathogens of potential impact on health, safety and the economy. <https://www.areasciencepark.it>; <https://www.ceric-eric.eu>

MIRRI-IT: The Joint Research Unit is mainly aimed at the implementation of the Italian node of MIRRI and the development of the Italian network of collections of microbial resources. <https://www.mirri-it.it/>

At national level, starting from 2024, 5 National Facilities, serving as technological hubs and incubators for developing and disseminating new tools and methodologies and for carrying out top-level research have been made available to the entire Italian scientific community at Human Technopole, a research institute set up by the Italian government in 2018 (<https://humantechnopole.it/en/national-facilities/>)

Website network of clinical trials (e.g. to facilitate the access to clinical trials) :

ItaCRIN is Italy's national node of the European Clinical Research Infrastructure Network (ECRIN). Coordinated by the Istituto Superiore di Sanità (ISS), it connects 15 Clinical Research Organisations (CROs) and Clinical Trial Units (CTUs) across the country. In Italy, several platforms and networks facilitate access to clinical trials for patients, researchers, and healthcare professionals. <https://www.itacrin.it/>

Other key related resources:

<https://eu-response.eu/>;
<https://www.ecraid.eu/>;
<https://www.edctp.org/>;
<https://www.combacte.com/>;
<https://vaccelerate.eu/>
<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments>;
https://commission.europa.eu/about/departments-and-executive-agencies/recovery-and-resilience-task-force_en%0d%0ahttps://commission.europa.eu/about/departments-and-executive-agencies/recovery-and-resilience-task-force_en;

Budget mobilisation mechanisms and funding sources

The information is not exhaustive and should be updated regularly.

Flexible funding is provided in case of emergency by several agencies (MUR, MoH, ISS, CNR).

Regarding specific COVID clinical research during the pandemics, the Tuscany Region - Directorate Health, Welfare and Social Cohesion has issued a regional call for financing public research projects in the field of COVID-19.

Basic Research

URL https://www.salute.gov.it/portale/temi/p2_3_ricerca.html
regional : <https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione>

funding for basic research accessible for industry? Yes

source of funding Public (research) agencies; Private industries/ philanthropic; Non-profit organisation

Applied Research

URL https://www.salute.gov.it/portale/temi/p2_3_ricerca.html
regional : <https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione>

funding for applied research accessible for industry? Yes

source of funding Public (research) agencies; Private industries/ philanthropic; Non-profit organisation

Translational Research

URL https://www.salute.gov.it/portale/temi/p2_3_ricerca.html
regional : <https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione>

funding accessible for industry? Yes
source of funding Public (research) agencies; Private industries/ philanthropic; Non-profit organisation

Clinical Research (in general)

URL https://www.salute.gov.it/portale/temi/p2_3_ricerca.html
regional : <https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione>

funding accessible for industry? Yes
source of funding Public (research) agencies; Private industries/ philanthropic; Non-profit organisation
phase funded? Phase 1; Phase 2; Phase 3

Clinical Research (in pandemic phase)

URL https://www.salute.gov.it/portale/temi/p2_3_ricerca.html
regional : <https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione>

accessible for industry? Yes
source of funding Public (research) agencies; Private industries/ philanthropic; Non-profit organisation
phase funded ? Phase 1; Phase 2; Phase 3

Innovation Projects

URL https://www.salute.gov.it/portale/temi/p2_3_ricerca.html
regional : <https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione>

funding for innovation projects accessible for industry relevant for infectious diseases?Yes
source of funding Public (research) agencies; Private industries/ philanthropic; Non-profit organisation

Important activities with different role and involvement on different partnerships under Horizon Europe Cluster 1 (Health) partnerships: For example with the Organisation of joint workshops and webinars to highlight topics of mutual interest. Alignment of calls and other activities (e.g. in capacity strengthening, dissemination of results, knowledge valorisation) targeting areas of joint interest: the therapeutic or diagnostic pipeline, drug resistance in relevant pathogens, regulatory issues, or health systems effects. Among them: Pandemic Preparedness; Personalised Medicine (EP PerMed), ERA for Health Research (ERA4Health), Transforming Health and Care Systems (THCS), Innovative Health Initiative Joint Undertaking (IHI JU); The Global Health EDCTP3 Joint Undertaking (GH EDCTP3 JU)

European initiatives within other EU funding programmes or clusters: Joint Action on Antimicrobial Resistance 2 (EU-JAMRAI 2); EIT Health; European Open Science Cloud (EOSC); 4Health Programme; European Investment Fund (EIF)

European Health Data Space ; EC General directorates, EU agencies, EU institutions; EC general directorates for Research and Innovation (DG RTD), Health and Food Safety (DG Santé), Agriculture and Rural Development (DG AGRI), Environment (DG ENV), Health Emergency Preparedness and Response Authority (HERA), European Centre for Disease Prevention and Control (ECDC); European Food Safety Authority (EFSA); European Medicines Agency (EMA); European Environment Agency (EEA)

R&I actors, authorities and activated processes that are activated in case of a health threat⁷

The information is not exhaustive and should be updated regularly.

R&I actors, authorities and ministries involved in case of an outbreak

Name	Description	URL
Agency for the Promotion of the European Research (APRE)	APRE maintains close relations with the most important national institutional actors active in the field of Research and Innovation, with a view to promoting the development and the internationalization of the Italian R&I system, by providing information, training and assistance services)	https://apre.it/en/homepage/
Fondazione Regionale per la Ricerca Biomedica (FRR)	FRR is a private law institution established by Lombardy Region to promote and enhance scientific research in the field of Life Sciences, particularly in the biomedical field	https://www.frrb.it/en/home
Italian coordinating structures	Coordinating structures for health needs and research are located at the Ministry of Health (MoH) and High Institute of Health (ISS) and Ministry of University & Research (MUR)	
Italian Medicines Agency (AIFA)	AIFA among others fosters and rewards investments in R&I by promoting and rewarding innovation	https://www.aifa.gov.it/en/
Italian National Agency for Regional Healthcare Services (AGENAS)	a technical-scientific body carrying out research and support activities, and Health Technology Assessment	https://www.agenas.gov.it/
Italian National Institute of Health (ISS)	ISS is the main center for research, control and technical-scientific advice on public health in Italy. Alongside the Ministry of Health, the Regions and the entire National Health Service (SSN), ISS guides health policies on the basis of scientific evidence. From prevention and health promotion to the fight against (infectious) diseases. https://www.iss.it/dmi-bando-riprei	https://www.iss.it/web/iss-en
National Research Council (CNR)	CNR is the largest public research institution in Italy	https://www.cnr.it/en
Ministry of Enterprises and Made in Italy (MIMIT)	MIMIT is responsible for the supply chain in Italy	https://www.mimit.gov.it/index.php/it/ministero
Ministry of Health (MoH)	The Ministry funds research and development of medical countermeasures. Moh and its technical and scientific advisory body, the Superior Council of Health is responsible for the healthcare system https://www.salute.gov.it/portale/temi/p2_3_ricerca.html & https://www.pnrr.salute.gov.it/portale/pnrrsalute/dettaglioContenutiPNRR-Salute.jsp?lingua=italiano&id=5831&area=PNRR-Salute&menu=comecambiassn	https://www.salute.gov.it/portale/p5_11.jsp
Ministry of University and Research (MUR)	The Ministry carries out the guidance, planning and coordination of national scientific and technological research among other functions	https://www.mur.gov.it/en
National Department of the Civil Protection (CPD)	CPD is involved in case of emergencies	https://www.protezionecivile.gov.it/en/
National Institute for Infectious Diseases Spallanzani (INMI - Rome)	The "Lazzaro Spallanzani" National Institute for Infectious Diseases (INMI) is an IRCCS, Institute for Scientific Research and Treatment, therefore research is an integral part of its DNA. The research activity that takes place within the Spallanzani is inspired by the continuity and integration between epidemiological, preclinical and clinical projects, and is translational research, i.e. capable of producing results that can be used in the short term	https://www.inmi.it/

⁷ https://www.pnrr.salute.gov.it/imgs/C_17_pagineAree_722_0_file.pdf

	<p>diagnosis or patient care.</p> <p>Generally speaking, the research activity of the Institute is organised into four main strands:</p> <ul style="list-style-type: none">• research activity on emerging infections such as COVID-19, on rare, difficult to diagnose or multi-resistant (MDR) pathogens, including control problems of infections and strategies to counter epidemics and support for international activities.• research activity on HIV disease, its pathogenesis, clinics, therapy, epidemiology and infection prevention. INMI is responsible for a clinical-assistance organisation that collects about 7,000 patients with HIV in active follow-up.• Research activity on viral hepatitis, which analyzes the virological aspects, the immune response, the molecular alterations underlying the development of cirrhosis, and the local epidemiology of viral hepatitis so that the healthcare offer is adequate to respond to evolving needs specific to local communities and the most fragile groups.• Research activities on tuberculosis, which deals with the epidemiological analysis of the disease with particular regard to the groups at higher risk and with the optimisation of therapeutic strategies for multidrug-resistant tuberculosis. Currently, the Institute has in its dotation the only Italian Biosafety Level 4 (BSL-4) laboratory and 5 Biosafety Level 3 laboratories (BSL-3). The Institute has a cryogenic bank that can host both 20 liquid nitrogen and 28 containers at -800 C, and it is supplied with a BSL-3 laboratory for sample preparation techniques necessary for the frosting process.	
PROMIS (International Health Brick Program)	Program promoted by the Ministry of Health with the aim of promoting healthcare in Europe and in the world, through collaboration between the Italian regions and international institutions.	https://promisalute.it
Regione Toscana	An organic and innovative system of research governance has been launched in Tuscany, and the latest regional health plans in Tuscany establish the importance of the promotion and development of research activities in the regional health service. "Bando Ricerca COVID-19 Toscana".	https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione
LifeScience Toscana Foundation		https://www.toscanalifesciences.org/en/
Regions/Autonomous provinces	Regions/Autonomous provinces implement pandemic preparedness plans; collect health data, may fund clinical trials	

Version July 2025



BE READY is responding to the call: HORIZON-HLTH-2021-DISEASE-04-06 “Building a European partnership for pandemic preparedness” under grant agreement 101057795.
Starting date: 01.06.2022. | End Date 31.05.2025

BE READY PLUS is responding to the call: HORIZON-HLTH-2024-DISEASE-17 “Pandemic preparedness and response: Maintaining and enhancing the preparatory work for a co-funded European partnership for pandemic”
under grant agreement 101195079. Starting date: 01.01.2025. | End Date 31.12.2025

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