

The competences for R&I and health are decentralised in Italy but the governance arrangements for Italy's COVID-19 response were coordinated at the national level. Italy's emergency response to the COVID-19 pandemic 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. The National Health Institute was also instrumental in coordinating the national disease surveillance system and using the network of reference laboratories to gather and analyse key data daily. The national Ministry of Health was the main authority for the health system response, coordinating with regional ministries. 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 2021 https://health.ec.europa.eu/system/files/2021-12/2021_chp_it_english.pdf)

In case of outbreak the institutional agencies Ministry of Health (MoH), Ministry of University & Research (MUR), National Research Council (CNR), are activated for R&I.

R&I Policies and Strategies

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

R&I strategy URL <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://publications.cnr.it/>

Regional : <https://www.regione.toscana.it/-/bando-ricerca-covid-19-toscana>

Country has R&I webpage on COVID-19; Antimicrobial resistance (AMR); Other

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

Name	URL	Short Description
COVID (Tuscany)	https://www.regione.toscana.it/-/bando-ricerca-covid-19-toscana	
COVID (Tuscany)	https://www.ars.toscana.it/aree-di-intervento/qualit%C3%A0-delle-cure/lotta-infezioni/431-nuovo-coronavirus.html	
Open Science Tuscany	https://www.toscanaopenresearch.it/en/	
Risorse Dati su Covid-19	https://dati-covid.italia.it/	A global, searchable index of data sources on the Italian Covid-19 situation
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?

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).

R&I Infrastructures

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-cnape/		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				
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 ESFRI initiatives relevant for infectious diseases

BBMRI; EATRIS; ECRIN; Other
ELIXIR (bioinformatics, big data, AI);
EBRAINS (brain research);
EURO-BIOIMAGING (advanced imaging);
INFRAFRONTIER (animal disease models);
INSTRUCT (structural biology);
ISBE (system biology)

Website network of clinical trials (e.g. to facilitate the access to clinical trials) the country is involved in

<https://eu-response.eu/>

<https://ecrin.org/>

<https://www.ecraid.eu/>

<https://www.recover-europe.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://vaccelerate.eu/>

Also in the context of European Partnerships on Personalised Medicine; Rare Diseases; Transforming Healthcare Systems

Budget mobilisation mechanisms and funding sources

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

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

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

Name	Description	url
APRE - Agency for the Promotion of the European Research	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/
CNR - National Research Council	The National Research Council (CNR) is the largest public research institution in Italy	https://www.cnr.it/en
FRR Fondazione Regionale per la Ricerca Biomedica	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
INMI - National Institute for Infectious Diseases Spallanzani	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 diagnosis or patient care. (located in Rome)	https://www.inmi.it/

ISS - Italian National Institute of Health	The Italian National Institute of Health (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/web/iss-en
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)	
LifeScience Toscana Foundation		https://www.toscanalifesciences.org/en/
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
MoH - Ministry of Health		https://www.salute.gov.it/portale/p5_11.jsp Research and innovation (salute.gov.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	https://www.regione.toscana.it/sst/aree-di-intervento/ricerca-e-innovazione



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