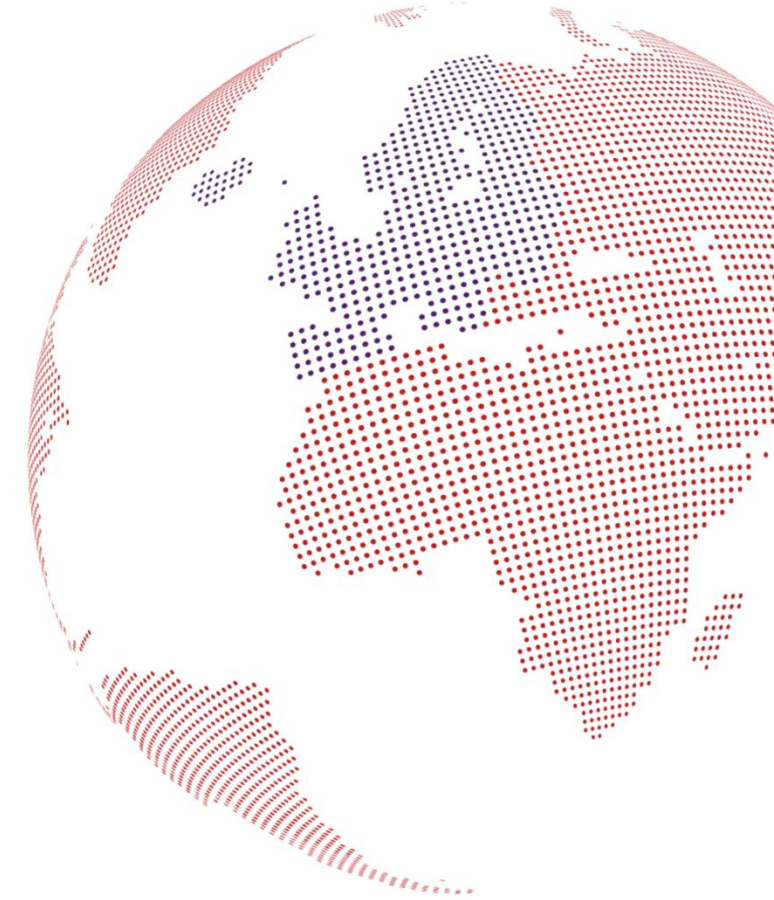




Access regulatory and clinical trial preparation support at no cost *for projects in infectious diseases**

27 September 2023 | 12 CET



**information on current calls
provided in the webinar*

eatris

 **ecrin**



ISIDORe has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement number 101046133



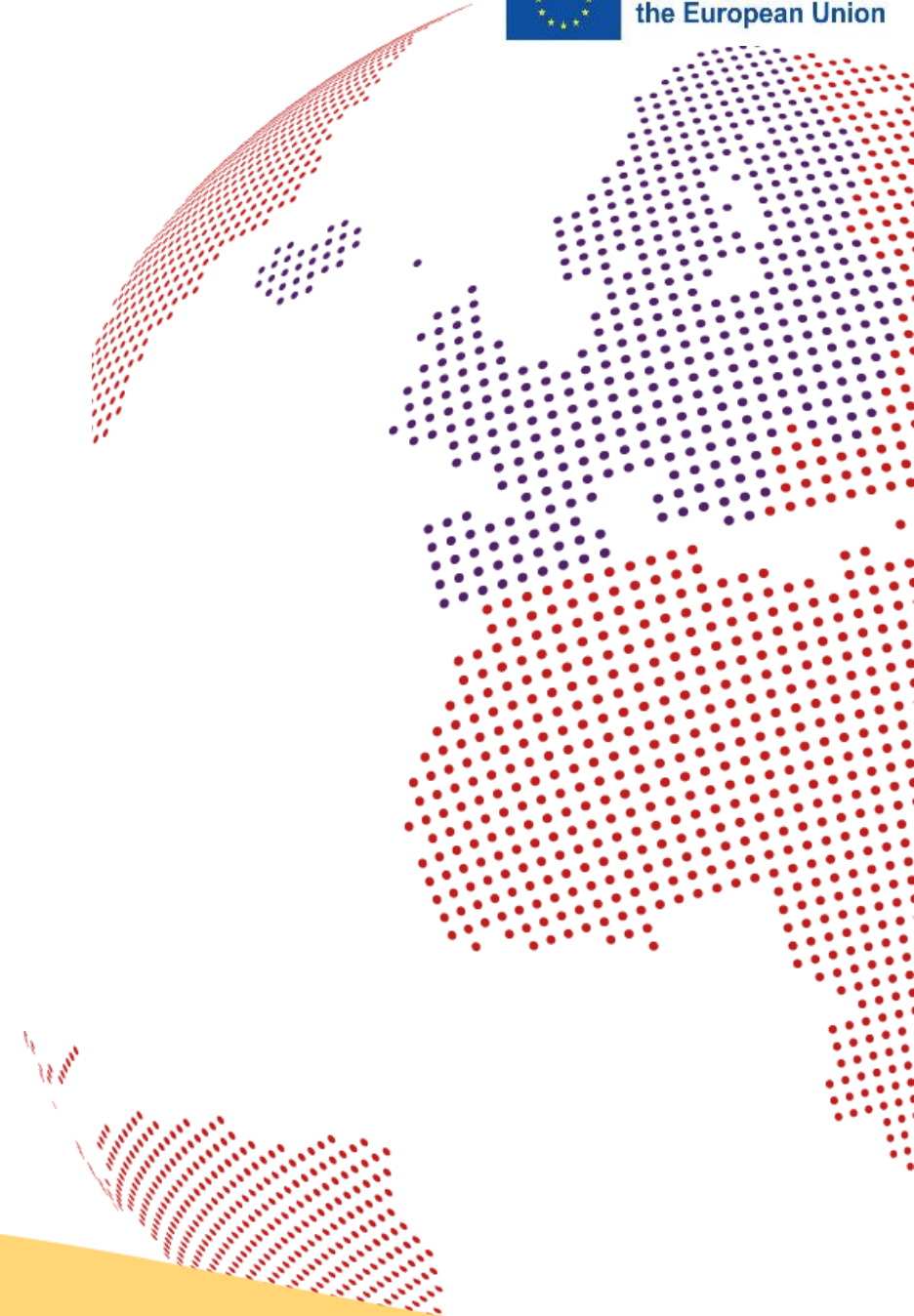
INTEGRATED SERVICES FOR INFECTIOUS DISEASE OUTBREAK RESEARCH

Sara Raza Khan, Project Manager

European Clinical Research Infrastructure Network (**ECRIN**)

David Morrow, Senior Scientific Programme Manager

European Infrastructure for Translational Medicine (**EATRIS**)



WHY ISIDORe?

THE COVID19 PANDEMIC:

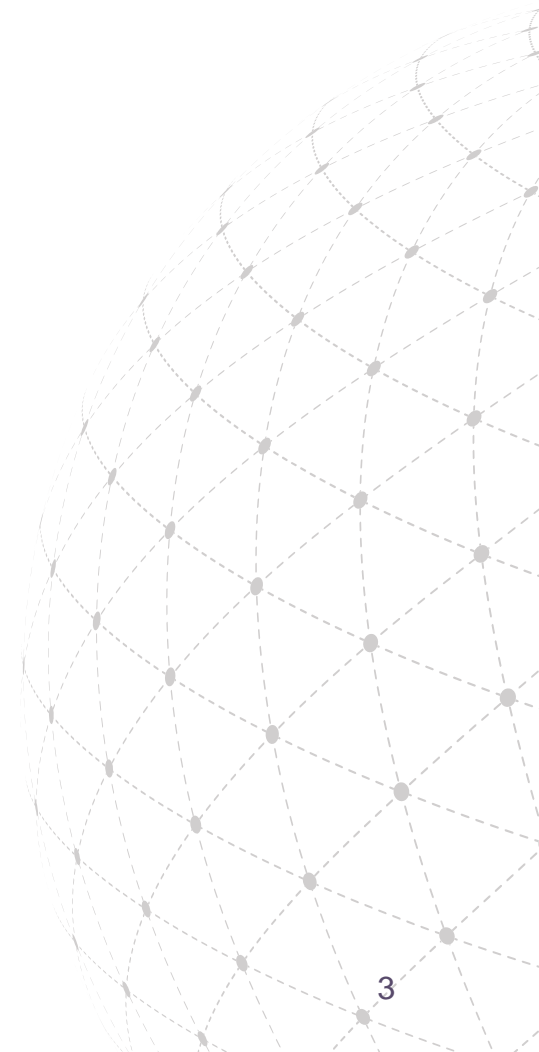
Crucial need for a higher capacity of preparedness and responsiveness to epidemic-prone pathogens in Europe and globally.



The European Health Emergency and Response Authority (HERA): Strengthen Europe's ability to PREVENT, DETECT, and RESPOND rapidly to health emergencies.



ISIDORe: the First HERA action to advance research in line with the European Bio-defence preparedness plan (HERA Incubator)



WHAT IS ISIDORe?

INTEGRATED SERVICES FOR INFECTIOUS DISEASE OUTBREAK RESEARCH



SINCE 2022, ISIDORe, THE HERA'S FIRST ACTION, SUPPORTS SCIENTISTS AND THEIR RESEARCH ON **EPIDEMIC- AND PANDEMIC-PRONE PATHOGENS THROUGH THE PROVISION OF RI SERVICES**

COORDINATION

erinha

European Research Infrastructure
on Highly Pathogenic Agents

DURATION

3 Years

FUNDING

€21 million (EC)

SERVICES

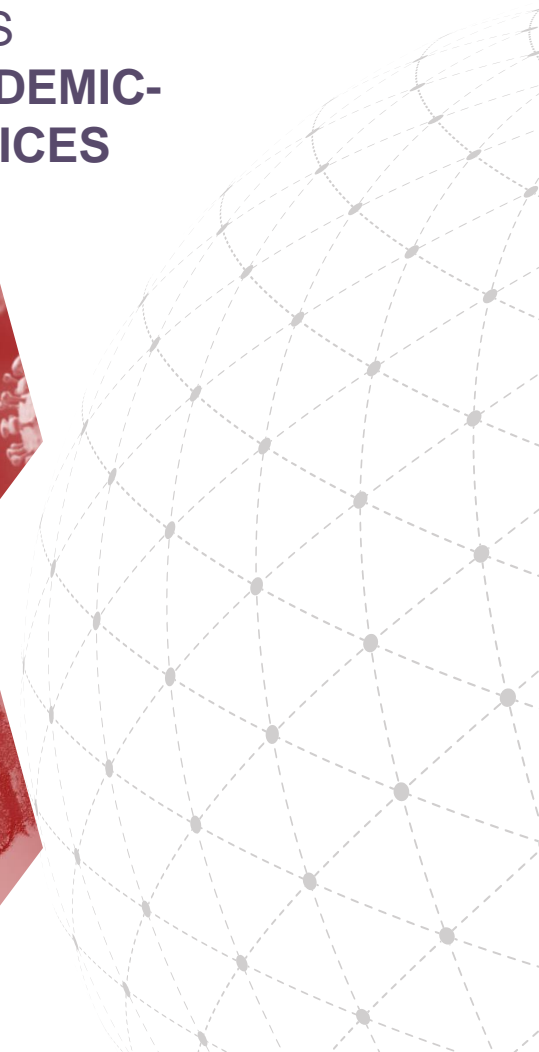
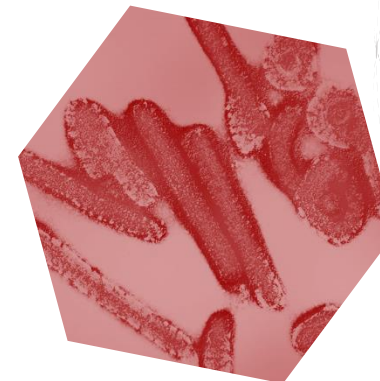
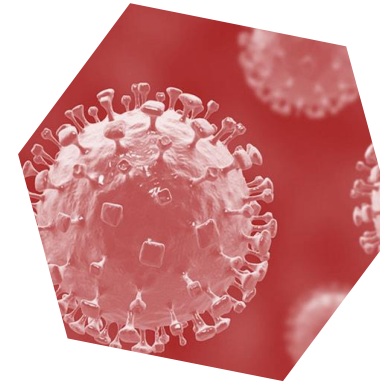
300+

PARTNERS

154

COUNTRIES

32



WHAT DOES ISIDORe OFFER?

ISIDORe Action supports Pandemic Preparedness & Response

FREE ACCESS TO RESEARCH RESOURCES, SERVICES AND EXPERTISE

We provide **free access** to a comprehensive One Health-driven **integrated portfolio** of high-quality research services (from structural biology to clinical trials) that support user projects.

ACCESS (TNA) CALLS FOR PROPOSALS

The provision of research services is organized through **calls for proposals** and independent review

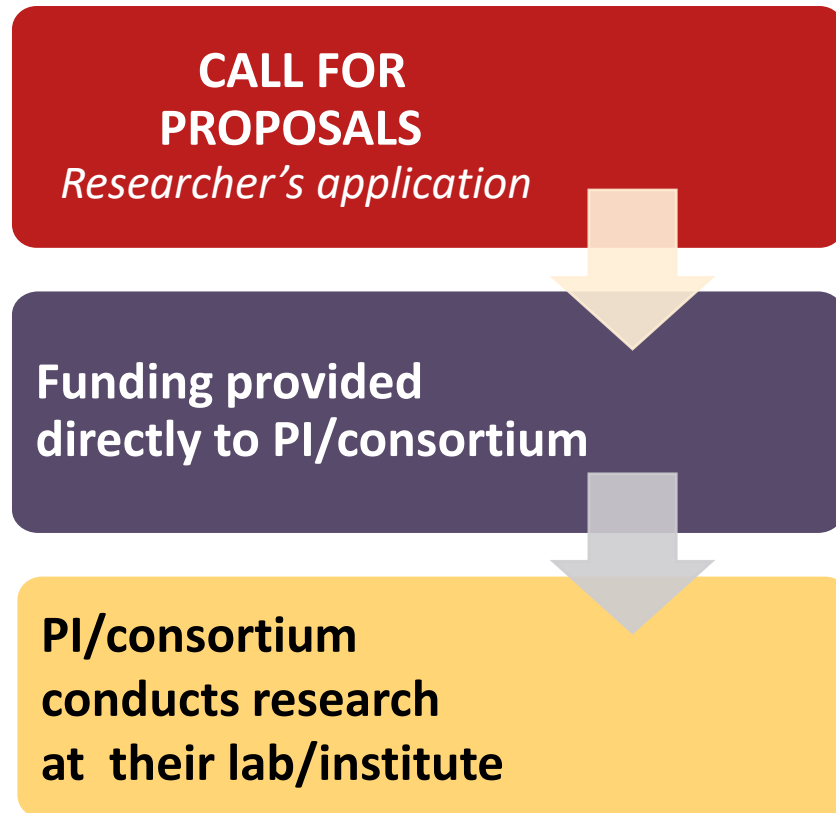
ELIGIBILITY

All researchers (public and private) are eligible to apply.

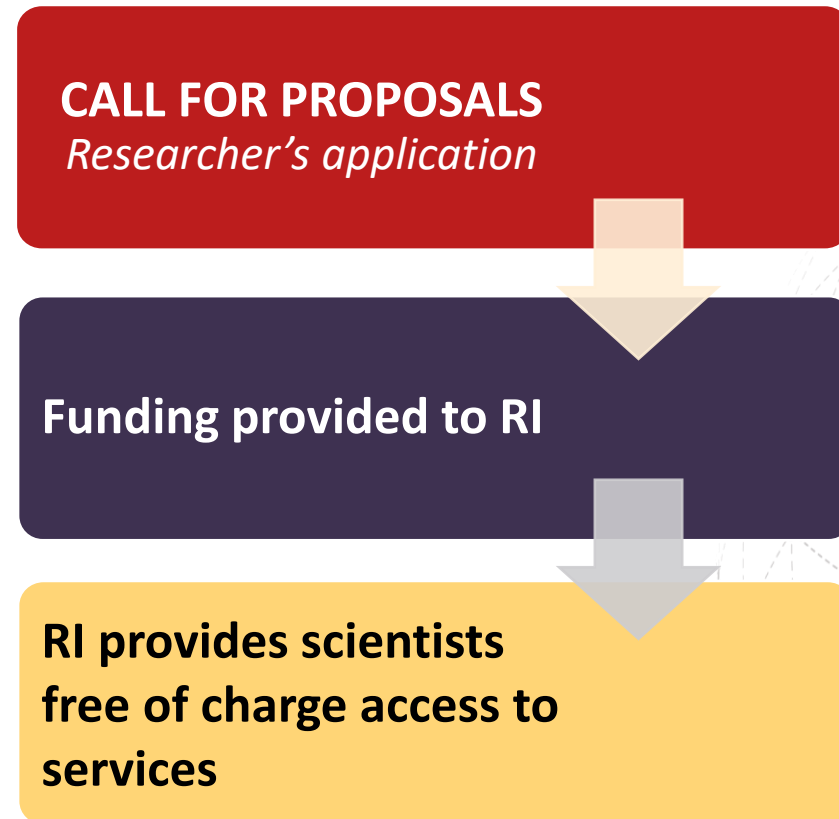
Calls are open worldwide

THE TRANSNATIONAL ACCESS MODEL

USUAL FUNDING MODEL



TNA FUNDING MODEL



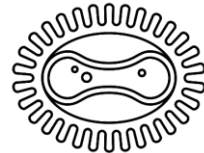
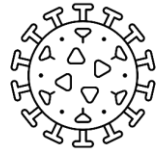
ISIDOR_e SCIENTIFIC PROGRAMME

OPEN CALLS

Open as long as funding remains

? RAPID RESEARCH RESPONSE CALLS

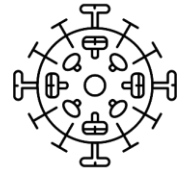
- **SARS-CoV-2 & COVID-19**
(Temporarily closed)
- **Monkeypox Virus**
(Already closed)



CLOSED FOR NEW APPLICATIONS




? PREPAREDNESS CALLS

- **Risk Group 4 Pathogens**
(Access to BSL4 services closed)
- **Respiratory Pathogens**
- **Vector-Borne Pathogens & their vectors**
- **Other Pathogens with Epidemic Potential**



ISIDORE Preparedness Programme

Preparedness Pathogens

RG4 PATHOGENS 	RESPIRATORY PATHOGENS (excl. SARS-CoV-2) 	VECTOR-BORNE PATHOGENS & THEIR VECTORS 	OTHER PATHOGENS WITH EPIDEMIC OR PANDEMIC POTENTIAL
Ebola virus	Zoonotic betacoronaviruses	Rift valley fever virus	Pathogen X
Marburg virus	Influenza A	Zika virus	Orthopoxviruses
Nipah virus	Y. pestis	Chikungunya virus	Non polio enteroviruses
Hendra virus	M. tuberculosis / bovis	West Nile virus	Polio enteroviruses
Lassa virus	C. burnetii	Dengue virus	
New World arenaviruses		Japanese encephalitis virus	
CCHF virus		Yellow fever virus	
		Tick-borne encephalitis virus	
		Plasmodium	
		B. burgdorferi	
		Leishmania	



ANALYTICAL SERVICES

PROVIDED BY
Instruct, Euro-BioImaging,
VetBioNet & Emergen, Infravec

Get access to cutting-edge services & technologies for structural biology, imaging & sequencing



CELL MODELS

PROVIDED BY
VetBioNet & ERINHA

Browse our extensive range of 2D & 3D models for characterizing disease infection & choose the best option for your research



IN VIVO MODELS

PROVIDED BY
VetBioNet, Transvac,
Infrafrontier & ERINHA,
Infravec

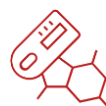
Find out about and get access to our wide range of in vivo models and expertise for advancing your research



IMMUNO-MONITORING & PROFILING

PROVIDED BY
EATRIS, VetBioNet, Infrafrontier,
Euro-BioImaging & ERINHA

State-of-the-art services for deciphering the immune response



SUPPORT FOR DIAGNOSTIC & THERAPEUTIC DEVELOPMENT

PROVIDED BY
EU-OPENSREEN & ERINHA,
Infravec

The best of chemical biology for developing the next prevention and intervention tools



SUPPORT FOR VACCINE DEVELOPMENT

PROVIDED BY
Transvac, VetBioNet & Instruct

Boost the development of your vaccine candidate.



CLINICAL SAMPLES

PROVIDED BY
BBMRI

Get access to human clinical samples from the world's biggest biobanking directory



REGULATORY ADVICE, TRIAL PREPARATION & ACCESS TO CLINICAL TRIALS

PROVIDED BY
EATRIS & ECRIN

Bring your countermeasure to the next level by getting support for market authorization, trial preparation & operations, and even access to clinical trials



SOCIAL SCIENCES & EPIDEMIOLOGY

PROVIDED BY
SONAR GLOBAL & Infravec

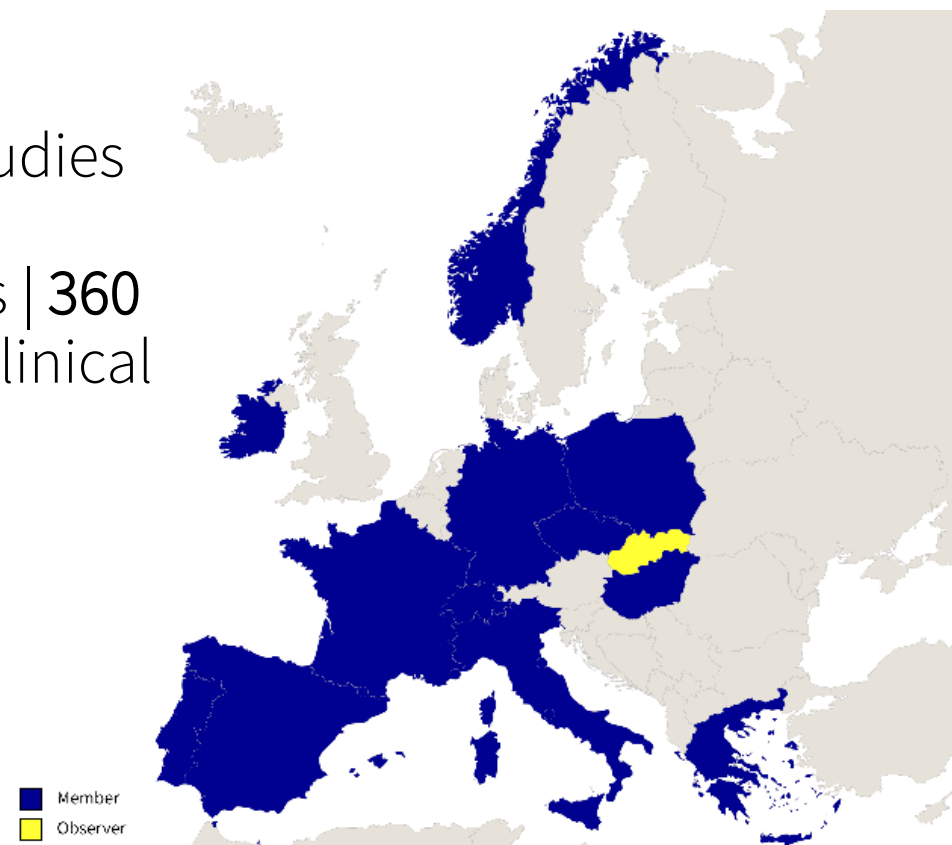
Efforts to tackle pandemics may be ineffective if complex social, political, economic and ecological contexts are not addressed. Find out about our social science expertise and services

ECRIN

<https://ecrin.org/>

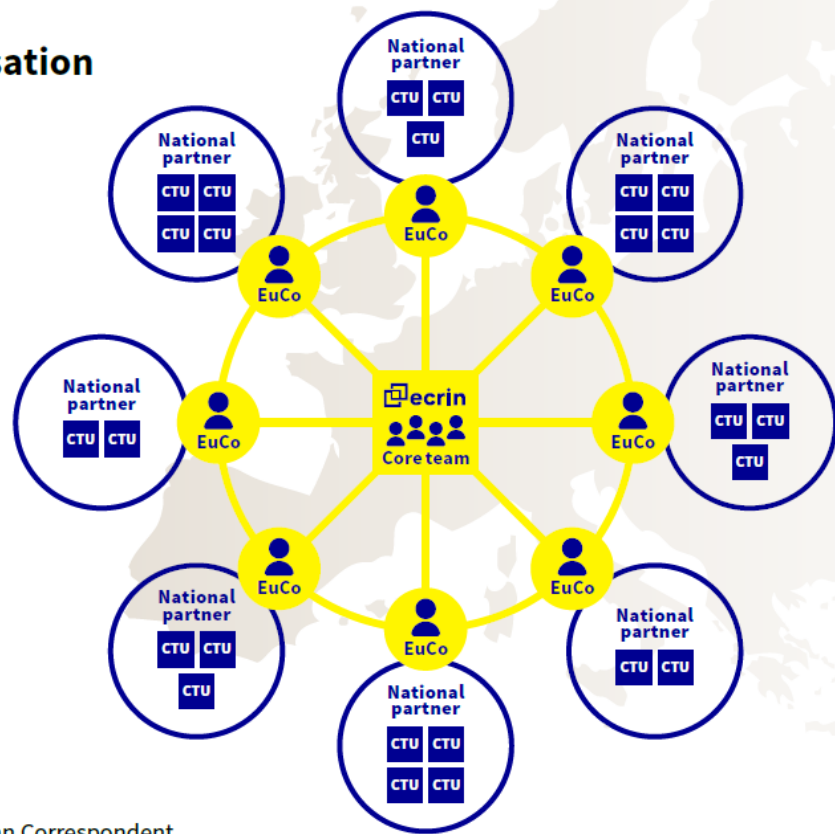
ECRIN's mission is to support Sponsors and investigators to conduct multinational clinical studies

- Distributed research infrastructure | **13** countries | **360** million EU citizens | **>120** Clinical Trial Units | **70** clinical studies supported | **50+** Infrastructure projects
- ISO 9001:2015 certified for its principal services



ECRIN Member & Observer Countries

Organisation



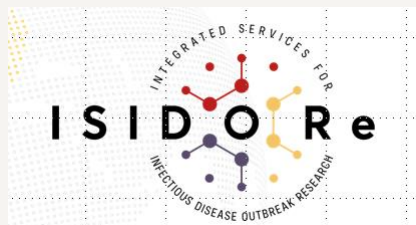
EuCo: European Correspondent
CTU: Clinical Trial Unit





GENERAL INFORMATION

- Outline roles and responsibilities
- Available funding sources
- Eligibility for funding and ECRIN support
- Regulatory inquiries



PLANNING

- Trial design and methodology
- Regulatory, ethical, and insurance requirements
- Funding application support
- Task distribution for multinational study management & selection of qualified CTUs
- Cost evaluation
- Protocol peer review
- Strategies for site selection and patient recruitment



OPERATIONAL COORDINATION

- Study management and coordination
- Regulatory and ethical submission
- Monitoring
- Vigilance
- Data management
- Statistical analysis



RISK ASSESSMENT

Assessment of feasibility, resources, and strategies for mitigation



EXPERTISE & OVERARCHING SUPPORT

Support to sponsors and PI throughout the maturation and execution of their ideas

ECRIN services in ISIDORE



HOW ECRIN SUPPORTS RESEARCHERS IN ISIDORE

ECRIN service: Support to Clinical studies

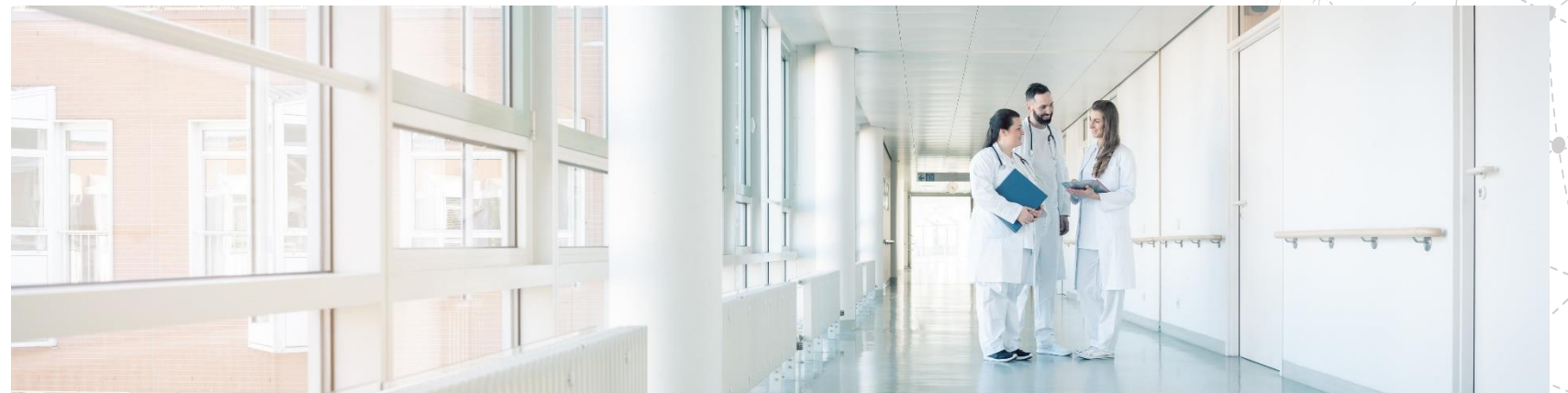
If you are a researcher, principal investigator or Sponsor developing a multinational clinical research proposal on any of the pathogens featured in the ISIDORE calls

You can reach out to ECRIN at no cost for:

- Guidance in planning and design of your clinical research proposals
- Expert advice in trial methodology and selection of optimal trial design



- Planning of clinical trial operations, encompassing regulatory / ethical requirements, informed consent
- Robust data monitoring plans, management and data sharing plans
- Expert guidance in key components of funding applications such as grant proposals and trial budgets
- Assistance in identifying possible funding mechanisms to continue your research
- Efficient task distribution for management of multinational studies
- Access to a range of open access tools (www.ecrin.org/tools)



EXAMPLES OF TNA SERVICES PROVIDED:

Project: Pilot study on Intranasal interferon beta for cognitive impairment secondary to COVID-19 for eligible long covid and dementia patients

ISIDORE service: Access to European Clinical Trials

Support provided: After expert review, the research proposal was shared with another EU clinical trial on long covid (outside of ISIDORE)

Project: Identify the regulatory requirements for clinical trial application and develop a summary protocol including trial design, methodology and implementation.

Support provided:

ECRIN experts provided information and advice to the team and assisted them in developing a protocol synopsis based on the regulatory requirements and their research objectives.

EATRIS Infrastructure

144+ academic and non-profit research institutes of excellence; more than half are university medical centres.

- **EATRIS Institutes**
- **EATRIS Members & Observers**



Participating countries:

Bulgaria, Croatia (observer), Czech Republic, Finland, France, Italy, Latvia (observer), Luxembourg, Norway, Portugal, Slovenia, Spain, Sweden, and The Netherlands

Our mission

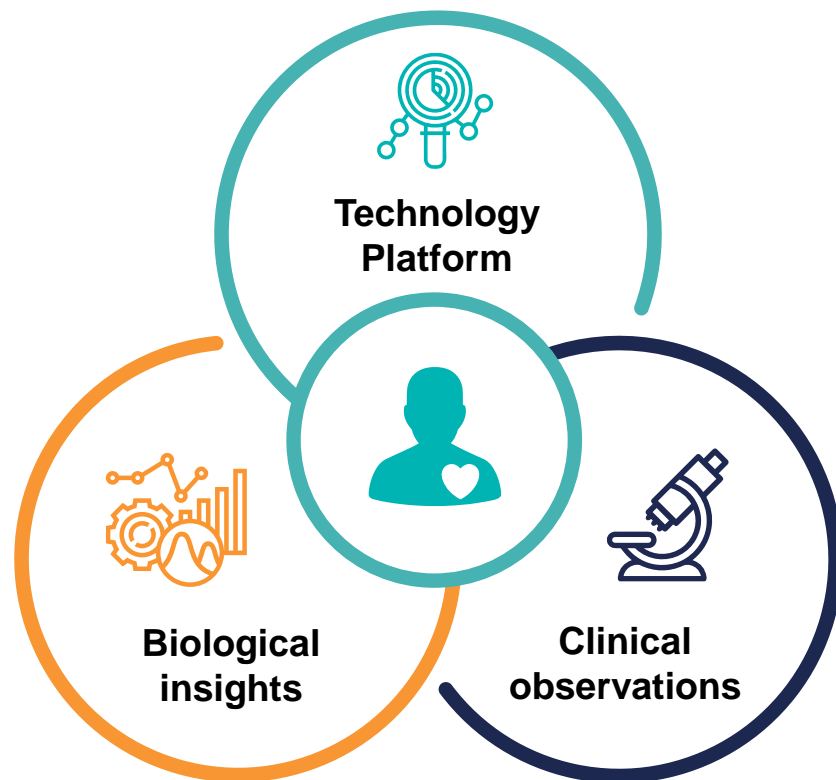


To accelerate the translation of research discoveries into patient benefit.

We **support, using our capacities and expertise** academia, industry, patients and policy makers.



What do we do



1

User access research and expert services

2

Develop new research tools

3

Provide education and training

4

Improve conditions for translation

What Regulatory services can we offer the ISIDORe applicant to support their product development?



WHAT CAN WE OFFER?

- Open discussion with a regulatory expert to discuss the right pre-clinical models to assess safety of their product
- Feedback and support on the drafting of a TPP or IMPD
- Support to apply for a scientific advice. What are the right questions?

*The **EATRIS regulatory service and support centre** is available to help guide you through this complex world, especially for complex and hybrid products for which clear regulatory guidance may not be available.*

Early assessment** of the potential requirements may **prevent unnecessary project delays, reduce extra costs and most importantly prevent penalties resulting from non-adherence to legal requirements.

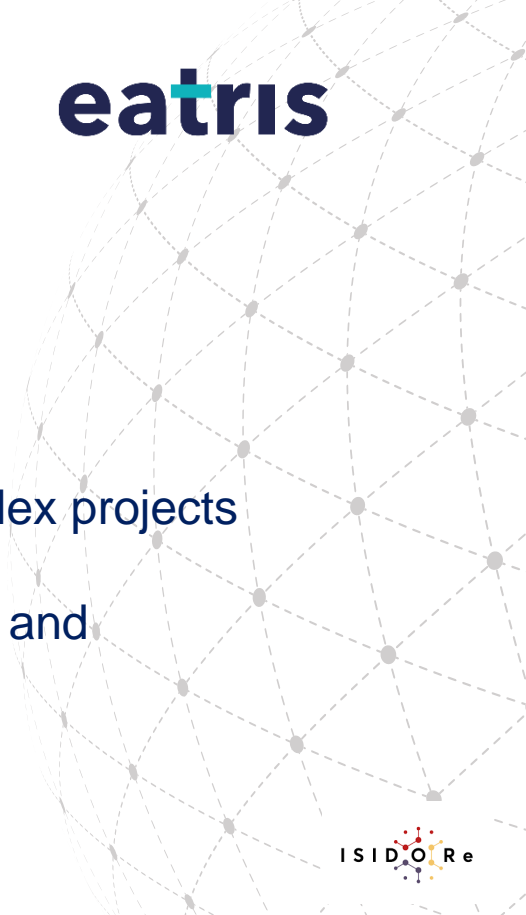
eatris





TYPES OF REGULATORY SUPPORT PROVIDED

- Assessment of regulatory requirement for marketing authorization
- Scientific advice for preparing an application to the European Medicines Agency
- Informal scientific advice with selected national competent authorities, for highly complex projects
- Pre-clinical and clinical development plan development – Target Product Profile (TPP) and Investigational Medicinal Product Dossier (IMPD)



EXAMPLES OF TNA SERVICES PROVIDED: REGULATORY

Project: *COVID-19 therapeutic in development with compound X as the active drug substance and is currently in a trial with a topical gel*

Goal:

- To confirm in vitro results of viral load reduction in a clinical setting through a single study to evaluate a Single Dose of compound X in Subjects With COVID-19

Regulatory Support required:

- Is a safety/tox study in animals required with the new formulation before submitting the CTA for the next clinical trial required ?
- Do we need to carry out dose finding in healthy volunteers or can we go directly into patients for the dose finding phase I study.

Regulatory Support provided:

- Advice and feedback provided to specific regulatory questions, Advice on the Scientific Advice process at NCA and EMA level, Support for drafting a scientific advice brochure with NCA where trial will be carried out.



EXAMPLES OF TNA SERVICES PROVIDED: IMMUNOMONITORING/IMMUNOPROFILING

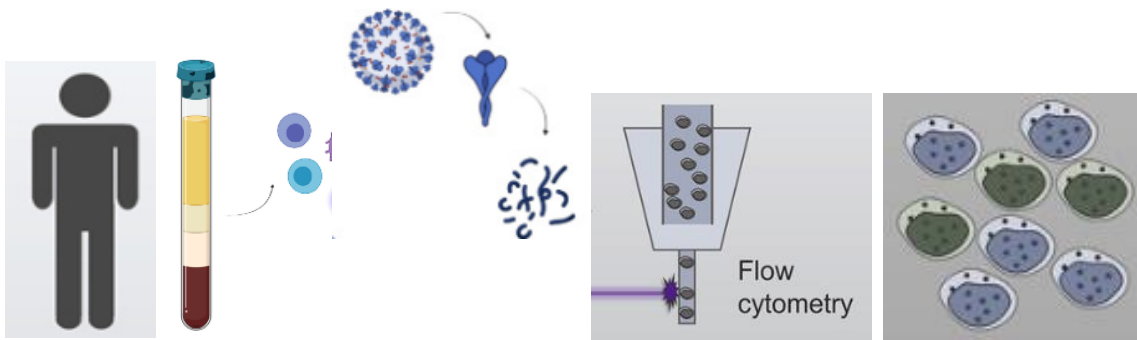
Project: *Assessment of COVID-19 vaccine effectiveness among healthcare workers*

Goal: To assess the immune response (quantification of SARS-CoV-2 specific T cells markers and cytokines) over time, as well as its several associations with SARS-CoV-2 Variants of concern (VOC) and strains, its mutations and/or deletions, clinical phenotypes of the hosts, and the severity of the disease, accounting for vaccination and other protective and risk factors.

Immunomonitoring service required: Quantification of SARS-CoV-2 specific T cells markers and cytokines in a cohort of XX people and its associations with SARS-CoV-2 VOCs and strains

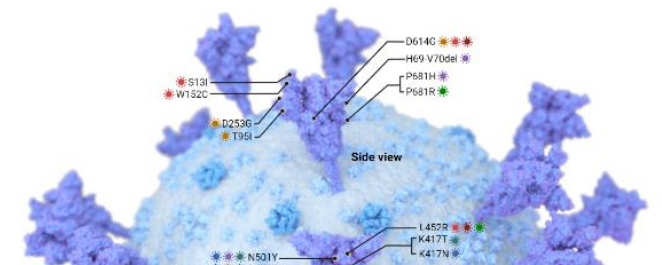
Immunomonitoring service provided:

- Quantification of markers and cytokines of SARS-CoV-2 specific T cells
- SARS-CoV-2 RNA sequencing (whole genome sequencing using Illumina technology)



The SARS-CoV-2 Variants of Concern Key Spike Protein Mutations

B.1.1.7 Detected: Dec. 14 2020 🇬🇧 UK	B.1.351 Detected: Dec. 18 2020 🇿🇦 South Africa	P.1 Detected: Dec. 4 2020 🇧🇷 Brazil	B.1.526 Detected: Nov. 2020 🇺🇸 USA	B.1.427 Detected: Dec. 2020 🇺🇸 USA	B.1.429 Detected: Nov. 2020 🇺🇸 USA	B.1.617 Detected: Feb. 2021 🇮🇳 India
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ISIDORe'S CORE: RESEARCH INFRASTRUCTURES (RIs)

Coordinator: **E**uropean **R**esearch **I**nfrastructure on **H**ighly pathogenic **A**gents

RESEARCH INFRASTRUCTURES

Facilities, resources and services **made available to the research communities** to conduct research and foster innovation **in their fields.**

Include: any tools that are essential to **achieve excellence in research and innovation.**



+ National surveillance network: EMERGEN



You can apply for ISIDORe services:

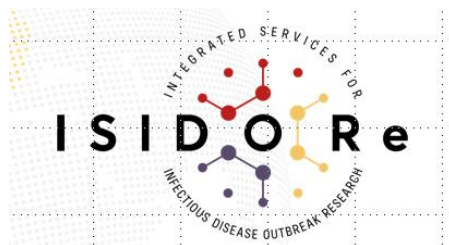
- **REGULATORY ADVICE, SUPPORT IN CLINICAL TRIAL PREPARATION**
- No cost advice and support
- Through the 4 calls in ISIDORe
 - Risk Group 4 pathogens
 - Respiratory pathogens
 - Vector-borne pathogens and their vectors
 - Other pathogens with epidemic potential



***THESE CALLS
ARE OPEN***

APPLY TODAY

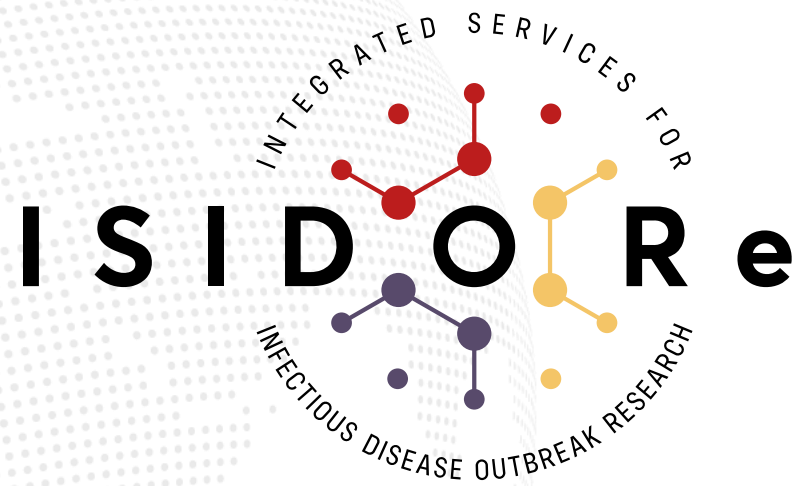
www.isidore-project.eu



contact@isidore-project.eu



Funded by
the European Union



THANK YOU!