

Research Infrastructures and **COVID-19** Research





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Responses to the questionnaire

ECRIN-ERIC (European Clinical Research Infrastructure)

ECRIN supports multinational clinical trials in Europe, enabling access to patients and medical expertise throughout Europe

SERVICE/S IMPLEMENTED

ECRIN provides support and operational services to the planning, design and management of multinational clinical trials in Europe

What stage in COVID-19 intervention your RI is addressing?

clinical research on treatments, diagnostics or prevention

- Instruments/databases involved:
- support to multinational clinical research, either interventional (clinical trials) or observational (cohorts), including regulatory/ ethics / data protection / data management / data monitoring / vigilance COVID clinical trial metadata repository
- How is the proposal submitted?

https://www.ecrin.org/activities/access-cost-policy

Who evaluates the proposal?

The ECRIN Scientific Board, the full protocol is reviewed by ECRIN peer-review committee (methodologists and pharmacologists)

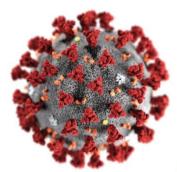
Is the submission continuous, or linked to a deadline?

Continuous submission

What is the estimated time from the submission to the access / service provision?

Fast track for the COVID trials (one week)

CHARACTERISTICS OF THE ACCESS



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Restrictions: The trial should be conducted in at least two ECRIN Member/Observer countries (CH CZ DE ES FR HU IRL IT NO PL PT SP), but additional countries are welcome.

In the case of analytical facilities, modality of access allowed:

If on-site access is allowed, is mobility support available?	
Is the access free for non-proprietary research?	NO
Is commercial access available at reduced prices?	YES
Are there limitations regarding the type of samples?	NO
Are there special requirements for shipment of the samples?	YES
Are there specific requirements regarding the preparation or	YES
handling of the samples?	

Additional comments related to the questions above: ECRIN supports trials sponsored by academic organisations as well as industry, in particular SMEs who lack the capacity to set-up and conduct multinational studies.

ACCESSIBILITY OF THE PUBLICATION AND DATA

Is there any requirement to publish in open access journals?	NO
Is the data generated associated to metadata and is it publicly available?	NO
If yes, what is the embargo period?	
Where is the data or metadata published? (e.g. in the institution's catalogue, in other open data repositories, etc).	Metadata are accessible through the metadata repository. The ECRIN-supported trials are committeed to share the personal, sensitive individual-patient level data according to a data sharing plan associated with the protocol.
Do you have further comments about data or metadata?	All the non-sensitive data are openly accessible, and the sensitive personal data have to be shared according to a pre-established data sharing plan, taking into account the informed consent and the GDPR provisions.