



E N E R G Y

**The Ean NEuro-covid ReGistrY
Consortium**

Version 04

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Collaborating Organizations:

Neurocritical Care Society

Promoter:

The Registry is promoted and endorsed by the European Academy of Neurology (EAN).

Table of Changes:

Date	Page/Section	Description of Change
July 29, 2020	Pg. 6 / procedure section	Sentence added which allows for inclusion of retrospective patient data
September 7, 2020	Pg. 7 Pg. 8 Pg. 13	Secondary objectives: Added "... and non-European countries" Methodology: "Included will be all COVID-19 patients whom the neurologists have been asked to visit or are available in the local registries and fulfilled the inclusion criteria. Both retrospective and prospective cases are eligible for inclusion." CRF: Added "Final COVID-19 status"
September 19, 2020	Pg. 8	Information on data sharing with third countries.
March 21, 2021	Pg. 6	The sentence " ... adjusting for demographics, comorbidities, centre and country" has been changed into " ... adjusting for demographics, comorbidities, vaccination, centre and country"
March 21, 2021	Pg. 11	Addition of info on vaccination at 6-month and 12-month visit
July 23, 2021	Pg. 3	Table with list of Participating Sites added:
July 21, 2021	Pg 14	Addition of date of visit and follow-up visits
July 21, 2021	Pg 14	Addition of 30 and 90 day follow-up incl. set of questions
July 21, 2021	Pg 14	Set of questions for 6- and 12-month follow-up combined, since identical
July 21, 2021	Pg. 14	Set of new questions referring to general symptoms added to

		the 6- and 12-months follow-up
July 21, 2021	Pg 14	Set of questions referring to new neurological symptoms at follow-up
July 21, 2021	Pg. 2	Physical site of database and data management changed to independent, professional company: The names Erich Kvas, Hermesoft, Austria Stefan Kalcher, Hermesoft, Austria added.
July 21, 2021	Pg 11	Data collection system changed from RedCap to Hermesoft's software (studienserver powered by medical framework)
July 21, 2021	Pg 11	Statistical analysis: data monitoring, data quality added, since these will be implemented on a professional level.
July 21, 2021	Pg. 2	Hermesoft Company, Graz, Austria added under the statistical analysis section, who will be in charge of data monitoring and data quality assurance
July 21, 2021	Pg. 8	Hermesoft data management company has been added in replacement of the medical University of Innsbruck under the Collection of data section
July 21, 2021	Pg 11	Hermesoft data management company has been added in replacement of the medical University of Innsbruck under the confidentiality section
July 21, 2021	Pg. 10	RedCap replaced by Studienserver powered by medical framework
August 18, 2023	Pg. 2	Ettore Beghi has been replaced by Maurizio Leone in the Core Scientific Committee.

August 18, 2023	Pg. 2	Pille Taba has been removed from the Core Scientific Committee.
August 18, 2023	Pg. 2	Maria Konti has been added to the Core Scientific Committee.
August 18, 2023	Pg. 2	The Enlarged Scientific Committee is now consisting of the Core Scientific Committee and the EAN Scientific Committee.
August 18, 2023	Pg. 2	Ettore Beghi has been replaced as a project monitor by Maurizio Leone
August 18, 2023	Pg. 2	Data Management title has changed to Clinical Data Management.
August 18, 2023	Pg. 2	Lalit Kaltenback has been replaced by Maurizio Leone in the statistical analysis, data monitoring and data quality control.
August 18, 2023	Pg. 3-4	The “Participating Registered Sites” list of the centers and the Primary Investigators has been updated.
August 18, 2023	Pg. 4	The list of “Collaborating Organizations” has been added.
August 18, 2023	Pg. 4	“Promoter” was moved from the main text, under the “Collaborating organisations”.
August 18, 2023	Pg. 11	Table of contents has been created and added.
August 18, 2023	Pg. 12	The paragraph title “Background & Rationale” has been changed to “BACKGROUND AND STUDY RATIONALE”.
August 18, 2023	Pg. 12	The content of the “BACKGROUND AND STUDY RATIONALE ” has been updated.
August 18, 2023	Pg. 12	The paragraph title “Objectives” has been changed to “STUDY

		OBJECTIVES AND HYPOTHESES”.
August 18, 2023	Pg. 13	An additional primary objective has been added: “c. To study the outcome of neurological manifestations in COVID-19”.
August 18, 2023	Pg. 13	An additional secondary objective has been added: “e. To register new and persisting symptoms up to a period of five years”.
August 18, 2023	Pg. 13	Two additional working hypotheses have been introduced: “4. COVID-19 infected patients with neurological manifestations show a distinctive neuro-phenotype profile ”5. Distinctive groups of neuro-phenotypes clusters among patients diagnosed with COVID-19 can be distinguished”.
August 18, 2023	Pg. 13	“Participants to the Registry” has been moved under “Study design” paragraph and the content has been updated.
August 18, 2023	Pg. 14	The age inclusion criterion for both “For COVID-19 patients with neurological signs, symptoms and/or defined neurological disorders” and for “For all COVID-19 patients” has changed from “Age 18 or older” to “Participants of all ages or ≥ 18 years when required by a specific Ethics”.
August 18, 2023	Pg. 14	A new inclusion criterion has been added both for “For COVID-19 patients with neurological signs, symptoms and/or defined neurological disorders” and for “For all COVID-19 patients”: “Participants should have contracted Covid-19 until the 30th of June 2023”.

August 18, 2023	Pg. 14	A new exclusion criterion has been added: "Participants who have contracted COVID-19 after the 30th of June 2023".
August 18, 2023	Pg. 14	The subparagraph "Procedure" has been changed to "Procedure – Responsibilities of the PIs and the participating sites".
August 18, 2023	Pg. 14	The duration scheme of the follow up has been updated: there are mandatory follow-ups 3/6/12 months and then annually up to 5 years.
August 18, 2023	Pg. 14	The 30 and 90 days NCC forms are abolished.
August 18, 2023	Pg. 15	The "Collection of Data" paragraph has changed to "ELECTRONIC DATABASE – COLLECTION OF DATA" and there are two new subparagraphs "Data Security and Durability" and "User levels, access control, users of the databases".
August 18, 2023	Pg. 17	A new paragraph has been added "New Project Proposals by PIs" accompanied by the subparagraph "Submission and Reviewing Process"
August 18, 2023	Pg. 20	In the "CASE REPORT FORM" paragraph, the following have been replaced: "NCC Questionnaire Supplementary", "30- and 90-day", "NCC Questionnaire Supplement", by " <u>3, 6, 12, 24, 36, 48, 60 months</u> ".
August 18, 2023	Pg. 22	The optional scales "Quality of Life After Brain Injury" and "Telephone Interview for Cognitive Status (TICS)" are replaced by the mandatory scales "Quality of Life After Brain Injury – Overall scale" and "Montreal Cognitive

		Assessment - BLIND (MoCA BLIND)" respectively.
August 18, 2023	Pg. 22-23	A new paragraph "CRF CHANGES" has been added to summarize the changes in the CRFs.
August 18, 2023	Pg. 23	A "REFERENCES" list has been added.
April 8, 2024	Pg. 3	The "Participating Registered Sites" list of the centers and the Primary Investigators has been updated.

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1 BACKGROUND AND STUDY RATIONALE

An unexpected outbreak caused by COVID-19 virus has devastated the world population and the global economy. After more than three years, the COVID-19 pandemic remains a global public health challenge. Among some of its most common clinical complications, neurological symptoms and diseases have been reported in up to one-third of affected cases. However, its distribution varies significantly in terms of prevalence, incidence, and phenotypical characteristics (Beghi et al., 2020).

Despite the exponential increase in the number of COVID-19 infections, information available on the full spectrum of the disease and on the associations between clinical data and patients' biomarkers are still insufficient (Calvet et al., 2022; Samprathi & Jayashree; 2021). Evidence suggests that COVID-19 strongly affects other organs in addition to the respiratory system, including the central and peripheral nervous system. The involvement of these systems is believed to be related to the direct action of the virus on the nervous tissue and to an indirect action through the activation of immune-mediated mechanisms (Moro et al., 2020). Along with this, the need for prolonged intensive care management in severe COVID-19 patients leads to adverse effects on the central and peripheral nervous system, such as the post Intensive Care Unit (ICU) syndrome and ICU acquired weakness (Quin, Hough, Andrews & Bunnell, 2022).

Until relatively recently, information available on the involvement of the nervous system during the outbreak was mainly based on observational studies (e.g., Moro et al., 2020). These sources are open to selection bias, although there are indicators that neurological complications in COVID-19 patients are associated with a worse outcome. In addition, both differences in the dissemination of the infection across Europe and variability of measures adopted to contrast the outbreak prevent a correct surveillance of the clinical characteristics of the infection, including the occurrence of neurological disorders.

Currently available information can provide a picture of the rich spectrum of symptoms, signs, and diagnoses associated with COVID-19 infection. However, in the light of the wide differences in timing and severity of the outbreak across Europe, it is impossible to define the association between the impairment of neurological functions and the outcome of the infection. Consequently, to adopt adequate preventing measures without a systematic collection of the information in a well-defined cohort of patients is very challenging. Only a registry can shed some light on the burden and general characteristics of neurological complications of the COVID-19 outbreak and the association of these complications with the demographic and clinical features of the affected individuals.

2 STUDY OBJECTIVES AND HYPOTHESES

2.1 Objectives

The main objective of this international Registry is to provide epidemiological data on neurological manifestations (symptoms/signs and diagnoses) in patients with COVID-19 infection reported by neurologists in outpatient services, emergency rooms, and hospital departments. The EAN registry can be implemented as *stand-alone* registry for COVID-19 patients or as *an addendum* to an existing registry not targeting neurologic signs and symptoms.

1. **Primary objectives** are:

- a. To evaluate the prevalence of neurological manifestations in patients with *confirmed* COVID-19 disease

- b. To assess the general characteristics of the neurological manifestations associated with COVID-19.
- c. To study the outcome of neurological manifestations in COVID-19

2. Secondary objectives are:

- a. To collect epidemiologic data on neurological manifestations of the COVID-19 infection in European and non-European countries
- b. To evaluate the prevalence of neurological manifestations in patients with suspected COVID-19 disease
- c. To study the outcome of neurological manifestations in COVID-19 patients (including the incidence of new neurological manifestations)
- d. To evaluate the incidence of new neurological manifestations during follow-up.
- e. To register new and persisting symptoms up to a period of five years

2.2 Working hypotheses

1. Neurological manifestations are relatively common in COVID-19 patients
2. There may be variability in neurological manifestations among different countries
3. Neurological manifestations and complications contribute to worse outcome in confirmed COVID-19 patients.
4. COVID-19 infected patients with neurological manifestations show a distinctive neuro-phenotype profile
5. Distinctive groups of neuro-phenotypes clusters among patients diagnosed with COVID-19 can be distinguished

3 STUDY DESIGN

3.1 Participants to the Registry

National Neurological Societies or divisions of Neurology from individual academic centres or hospitals can apply to participate to the ENERGY Consortium.

3.2 Methodology

Neurologists are asked to implement this study protocol in their institution/clinic, to assess and record demographic and other data, neurologic symptoms and signs according to the annexed electronic Case Record Form (eCRF) in confirmed and suspected COVID-19 patients. Included will be all COVID-19 patients whom the neurologists have been asked to visit or are available in the local registries and fulfilled the inclusion criteria. Both retrospective and prospective cases are eligible for inclusion.

The minimum requirement is to register COVID-19 patients with neurological symptoms and/or signs and/or defined neurological disorders (see inclusion criteria). However, the inclusion of ALL patients with confirmed COVID-19 infection is encouraged to provide the numbers for the calculation of the fraction of the affected population attributable to neurological disorders and the comparison of the overall spectrum of the disease in people with and without neurological manifestations. In centres accepting to include all COVID-19 patients, another physician may be assigned as the person in charge of registration.

3.3 Inclusion criteria

For all COVID-19 patients:

- Participants of all ages or ≥ 18 years when required by a specific Ethics Committee.
- Symptoms suggesting COVID-19 infection OR confirmed COVID-19 infection.
- Participants should have contracted Covid-19 until the 30th of June 2023.
- Provided informed consent (according to the requirements of local regulatory agencies).

For COVID-19 patients with neurological signs, symptoms and/or defined neurological disorders:

- Participants of all ages or ≥ 18 years when required by a specific Ethics Committee.
- Symptoms suggesting COVID-19 infection OR confirmed COVID-19 infection.
- Participants should have contracted Covid-19 until the 30th of June 2023.
- Neurological evaluation/consultation
- Provided informed consent (according to the requirements of local regulatory agencies).

3.4 Exclusion criteria

- Symptoms suggesting other (pulmonary/systemic) infection than COVID-19 AND other confirmed infection.
- Participants who have contracted COVID-19 after the 30th of June 2023.

3.5 Procedure – Responsibilities of the PIs and the participating sites

Patients' inclusion can be performed prospectively, at the time of the visit or at patient's discharge, whichever is most convenient; or retrospectively, provided that all inclusion criteria are satisfied. Visits can be performed anywhere in the context of health care facilities (outpatient services, emergency rooms, hospital departments). If at the time of the visit, the clinical picture of the patient is incomplete, the neurologist is invited to contact the caring physician upon discharge to complete the eCRF. The collection of the data will be kept as minimum as possible to prevent attrition and loss of data due to the constraints posed by the outbreak. No additional investigations are needed besides a detailed neurological examination and common variables recorded in this pandemic, including status of vaccination as of July 2021. A series of essential scales should also be administered. The registration of the patients will continue until the end of the outbreak.

The PIs and the participating sites are responsible to follow up all registered patients with neurological symptoms up to 5 years, with telephone calls at 3/6/12 months and then annually up to 5 years to verify clinical conditions, functional abilities, and identify neurological manifestations that might have occurred after the acute phase of the disease.

The Primary Investigator/ a neurologist (or a designated partner of the local study team) will oversee the follow-up. A guide is annexed to this protocol to define each variable and facilitate data collection in the eCRF.

3.6 Statistical analysis plan

Descriptive statistics will be performed on all variables collected in the registry. Inferential statistics will include univariate and multivariate analyses. Cross-tabulations will be performed for each symptom, sign and neurological diagnosis against demographics and the other clinical variables, including comorbidities and the main complications of infection. These data will be presented in the entire sample and for each country separately. The neurological diagnoses made at the time of the infection will be contrasted to the status at last observation (recovered, alive with functional impairment, dead). The prevalence of neurological symptoms, signs and diagnoses will be calculated using the number of neurological consultations as denominator and symptoms/signs and, separately, neurological diagnoses as a group. Multivariate analyses will be also performed using logistic regression models with status at last observation (alive with or without functional impairment/dead) as the dependent variable and neurological diagnoses as the independent variables, adjusting for demographics, comorbidities, vaccination, centre and country. Follow-up data will be analysed in survivors with Kaplan-Meier curves using the occurrence of a neurological diagnosis as the outcome variable and demographics and comorbidities as prognostic predictors. Comparisons will be tested with Log-rank and independent prognostic predictors will be assessed using Cox's hazard models, adjusting for centre and country. The significance will be set at the 5% level ($p=0.05$).

Sample size calculation. The primary endpoints of this registry are to determine the prevalence and the general characteristics of neurological manifestations in COVID 19 patients. The hypotheses of this registry are exploratory; hence a sample size calculation has not been performed.

3.7 Benefit and risk ratio

ENERGY will not interfere with the diagnostic and therapeutic decisions made by the attending physicians for the management of the disease. There may be a benefit for patients undergoing neurological examination by early identification of neurological symptoms and signs which may result in a specific treatment. Therefore, the detection of complications may lead to a better management of patients included in this registry.

Consecutive data collection will result in a better understanding of neurological disease manifestations and complications in suspected and confirmed COVID-19 positive patients. This will be important for an early identification of core neurological symptoms during the pandemic.

4 ELECTRONIC DATABASE – COLLECTION OF DATA

Routinely captured data will be collected in a web-based eCRF (studienserver powered by medical framework) and stored in a password-protected database not accessible directly from the internet. The password is provided to every participating site. Each centre will be assigned a numeric code generated by the central database. The data will be securely stored at the Hermesoft, Graz, Austria, data management system. Hermesoft is an independent professional company contracted by the EAN central office.

The collection of data will be monitored in order to guarantee plausibility and high data quality. All procedures will comply with the EU Regulation 2016/679 (DSGVO, *engl.* GDPR) on the protection of natural persons regarding personal data processing and movement.

4.1 Data security and durability

Hermesoft study server is a highly secure data system which gets an automatic backup every 6 hours, and this copy is stored for one month. Additionally, a backup is done once a day and held without time limit. The database is generated as a study server powered by a medical framework, with external firewall blocks at all ports except HTTP(S) and VPN. Back-ups occur four times per day to a FTP server in the server house. External back-ups occur at the data centre and by a back-up provider. The Client server transfer per SSL is encrypted at 256 bit.

4.2 User levels, access control, users of the databases

The centers are responsible for selecting the user level of each database user which corresponds to the access control that they can have. The available roles are:

1. Primary Investigators: Users are allowed to add, modify and delete patients and visits of their own center and request new users, user changes and user deletion for their own center.
2. Data Managers: Users are allowed to add, modify and delete patients and visits of their own center.
3. Study Nurses: Users are allowed to add and modify patients and visits of their own center.
4. Data Readers: Users are allowed to read and export data for their own centers.

5 ETHICAL STANDARDS

The Primary Investigators (PIs) will ensure that the study is conducted in full conformity with the Declaration of Helsinki and Good Clinical Practices.

5.1 Ethics committee

The protocol will be submitted by the PIs to the local ethics committees (ECs). Any amendment to the protocol will require review and approval by the EC before the changes are implemented to the survey. Only individual data collected after the patient's informed consent will be used. Every eligible patient will be assigned an anonymized code.

5.2 Data confidentiality

Participants' and centres' confidentiality is strictly held in trust by the participating investigators. All medical or administrative staff with an access to the data is subject to a duty of confidentiality and data protection. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidentiality agreement protocols.

The study sponsor (European Academy of Neurology) and representatives of local authorities may inspect all documents and records required to be maintained by the local investigator for the participants in this registry. Research data of the registry, which is for purposes of statistical analysis and scientific reporting, will be transmitted to the Data Managers and the Statisticians of the registry. For this purpose, data will be de-identified and anonymized at input into the eCRF by the local centres/PIs. Individual participants and their research data will be identified by a unique identification number. The eCRF system used by clinical sites and by research staff will be secured and password protected. In the situation when a centre would be temporary not able to access the eCRF or complete it, a paper-based CRF will be available on demand. To keep administration and data correctness on a high level, this possibility should only rarely be used. These records will be

entered in the eCRF at the EAN central office in collaboration with the research staff of Hermesoft data management company and the Mario Negri Institute of Milan.

5.3 Data sharing & ownership

Where ENERGY is an addendum to other registries or databases, formal collaborations can be activated with European and international organisations to share common variables in the intent to provide a broad European and even worldwide picture and favour comparisons. For countries with independent registries/databases and that wish to share their data but are unwilling to use this registry, data will be compared in aggregate using pre-specified statistical plans. The data collected by individual centres will be accessible to these centres without restriction. All participants should be registered as active members of the EAN Neuro-COVID Registry Consortium.

The data collected can be also used to test scientific hypotheses forwarded by any active member. However, these hypotheses should be illustrated in ad-hoc protocols to be submitted for approval to the Registry Core Scientific Committee. The scientific reports should be published on behalf of the EAN and the affiliated neurological societies.

Participating sites will be informed of any data sharing agreement with organisations in countries not associated to the European Union.

5.4 Publication, and Authorship

Data will be made available to the scientific community by means of abstract or scientific papers submitted to peer-reviewed journals. Authorship of the main manuscript will follow the ICMJE recommendations that base authorship on the following four criteria:

- Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work, AND
- Drafting the work or revising it critically for important intellectual content, AND
- Final approval of the version to be published, AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

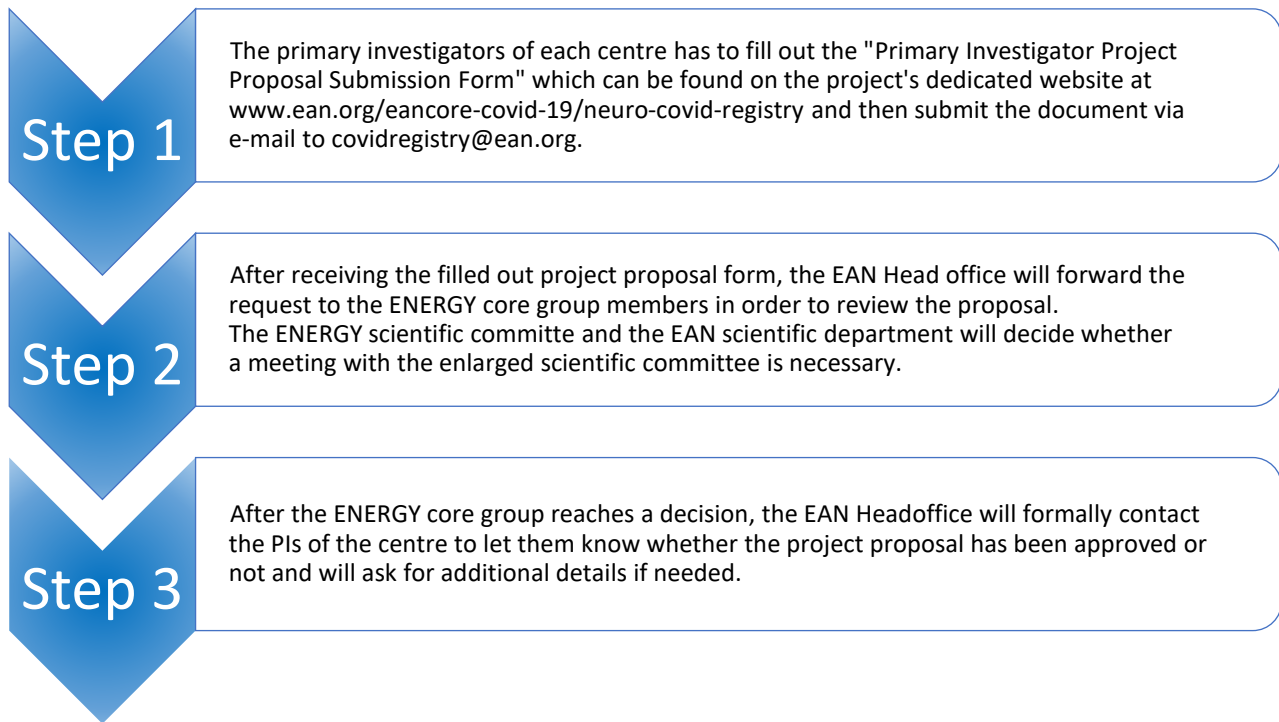
A writing committee composed by the Core Scientific Committee will draft the work and will be authors of the manuscript. All publications will be made in the name of ENERGY Consortium. All those who satisfy the criteria for authorship will be listed as authors. Each centre will be mentioned at least by the name of one author and listed “on behalf of the ENERGY consortium” in the main publications in PubMed. Additional authors will be listed based on the contribution of each site to the registry. Each author’s contribution within the Consortium will be specified.

6 NEW PROJECT PROPOSALS BY PIs

As the database has reached a point where extensive information can be provided on clinical data of more than 3500 patients with a COVID-19 infection presenting neurological complications, the

EAN has introduced an open call for the primary investigators from each of the ENERGY centres to submit their project proposals on further statistical analyses of the data that could be performed.

6.1 Submission and Reviewing Process:



The PIs are welcome to submit their project proposals at any time all year round.

7 CASE RECORD FORM

Centre ID

Patient's code

Date of visit

Site of visit

- Hospital
- Emergency room
- Outpatient service
- Other (spec)

Year of birth

Sex

Height

Weight

Smoking (no/yes)

Source of contagion

- Occupation
- Family member
- Social
- Travel
- Other (specify)

Date of first symptoms of infection

Final COVID-19 status (Suspected/Confirmed/PCR negative/PCR positive -oropharyngeal AND/OR serum AND/OR CSF-/Antibodies positive/Other, specify)

Comorbidities in history (no/yes)

If yes, check all that apply

- Arterial hypertension
- Diabetes
- Cardiovascular disease
- Chronic kidney disease
- Chronic liver disease
- Chronic bronchial/pulmonary disease
- Anemia
- Cancer
- Immune-mediated disease
- Other non-neurological (specify)

Neurological disease Premorbid Modified Rankin Scale

Relevant COVID-19 complications (not present in history) (No/Yes)

If yes, check all that apply

- Dyspnea
- Pneumonia
- Cardiovascular disease
- Renal insufficiency/dialysis
- Coagulation disorder/disseminated intravascular coagulopathy
- Septic shock
- Extracorporeal membrane oxygenation
- Other (specify)

Hospital admission (no/yes)

ICU admission (no/yes)

Mechanical ventilation (No/Yes)

New neurological symptoms/signs/diagnoses (no/yes)

If yes:

Date of onset of neurological symptoms/signs

Check all that apply and state if related/unrelated to COVID-19

- Headache
- Hyposmia/hypogeusia
- Dysautonomia
- Vertigo
- Myalgia
- Sleep disturbances
- Excessive daytime sleepiness/hypersomnia
- Cognitive impairment
- Dysexecutive syndrome
- Hyperactive delirium
- Hypoactive delirium/acute encephalopathy
- Stupor/coma
- Syncope
- Seizures/status epilepticus
- Meningitis/Encephalitis
- Stroke
- Movement disorders
- Ataxia
- Spinal cord disorder
- Peripheral neuropathy
- Other (specify)

Diagnostic tests

- CSF (No/Yes)
- CT/MRI (No/Yes)

Outcome

- Modified Rankin Scale at discharge
- If patient died, date of death
- If death, autopsy (No/Yes)

Follow-ups

3, 6, 12, 24, 36, 48, 60 months

Date of follow up

30 Day Mortality. Was the patient alive at 30 days after hospital discharge (Yes/NO)

Date of follow-up

- Modified Rankin Scale
- Vaccination (No/Yes)
- If Yes, specify name of vaccine and number of shots, with dates
- Occurrence of new neurological issues (No/Yes)
- If yes, date of onset and specification
- If patient died, date of death
- If death, autopsy (No/Yes)
- Persistence of symptoms after the acute phase.

Symptom/Sign (Persisting/resolved/ If resolved, date (Month/Year)):

- Fatigue
- Hypersomnia/EDS*
- Insomnia
- Headache
- Muscle pain
- Altered smell
- Altered taste
- Breathing problems
- Chest pain
- Palpitations
- Impaired concentration
- Impaired memory
- Hearing impairment
- Visual impairment
- Pain/Numbness (indicating PNS)
- Depression
- Anxiety
- Altered physical fitness
- Altered quality of life
- Other (specify)

*EDS: Excessive daytime sleepiness

- New neurological symptoms after the acute phase of COVID infection.

Disease (persisting/resolved/date of onset (Month/Year)):

- Demyelinating or other inflammatory white matter lesions
- Dementia/other cognitive disorders
- Dysautonomia
- Hemorrhagic Stroke
- Hypoxic ischemic brain injury
- Ischemic Stroke
- Meningitis
- Parkinson's disease/Parkinsonism
- Motor Neuron Disease

- Myelopathy/Spinal Cord Disease
- Myopathy
- Neuromuscular junction disorder
- Non-traumatic subarachnoid haemorrhage
- Polyneuropathy
- Polyradiculoneuropathy (GBS)
- Radiculopathy/Plexopathy
- Seizures/Epilepsy
- Toxic/Metabolic Encephalopathy
- Other neurological (specify)_____
- Post-COVID Headache
- Post-COVID fatigue
- Post-COVID sleep-wake disorder*

*insomnia, hypersomnia, EDS, narcolepsy, parasomnias

Attendance of periodical control visits for pre-existent diseases:

- Does the patient attend periodical control visits?: (Yes/No/)

If no, please select the most suitable choice.

- a. Because of fear of in-hospital infection
- b. Inefficient leading by family practitioners or other doctors in primary level /_/_
- c. Disrupted functioning at contact center /_/_
- d. Because of milder symptoms /_/_
- e. Lack of family members or bystanders to activate emergency services /_/_
- f. Lack of contact with others /_/_
- g. Because of warning about stay-at-home and social distancing practices /_/_

- Mandatory new Scales:

- Insomnia Severity Index
- Epworth Sleepiness Scale
- Fatigue Severity Scale
- Quality of Life After Brain Injury – Overall Scale
- Montreal Cognitive Assessment – BLIND (MoCA BLIND)

8 CRF CHANGES

1. Patient CRF:

Additional visit type “End of Study”. The centers will have the opportunity to end the study for patients for the following reasons: “death”, “withdrew consent”, “other, please specify”.

2. Follow-up CRF:
 - a. The following scales are mandatory and their questions are integrated into the follow-up CRF:
 - i. Insomnia Severity Index
 - ii. Epworth Sleepiness Scale
 - iii. Fatigue Severity Scale
 - iv. Quality of Life After Brain Injury – Overall Scale version (QOLIBRI)
 - v. Montreal Cognitive Assessment – BLIND (MoCA BLIND)

9 REFERENCES

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