Project Acronym: NicAb

Project title: Novel biomarkers in neurological and psychiatric disorders: autoantibodies to neuronal nicotinic acetylcholine receptors

Co-ordinator: Tzartos NeuroDiagnostics (Socrates Tzartos and John Tzartos)
Partner 2: Fondazione IRCCS Istituto Neurologico "Carlo Besta", Milan (Renato Mantegazza)
Partner 3: Dep. of Psychiatry and Psychotherapy, University of Magdeburg (Johann Steiner)

DATA MANAGEMENT PLAN – Final Version

DMP component	Issues to be addressed
1. Data summary	The purpose of the data collection and generation is to achieve the objectives of the project, i.e. to detect anti-AChR antibodies in autoimmune encephalitis and related diseases, in psychiatric disorders, and to study the function of these antibodies Data collection is obligatory for the objectives of the project Our data include clinical data of the patients, and laboratory data to be obtained by the performance of specific tests Existing data were re-used, in order to combine them with novel data and draw improved conclusions. Also, they may be used upon new improvements of our methodologies. The clinical data were derived mostly from the Milan (P2) and Magdeburg (P3) partners. The data were derived mostly from the Athens (P1) partner The study involves samples from about 2,500 patients. Our data will be useful to patients and their clinicians.
2. FAIR Data 2.1. Making data findable, including provisions for metadata	Our data (strictly anonymous) will be available to any researchers who wish to study them, upon request. Identifiability of data: The most important new data (i.e. discovery of novel antibodies in neuropsychiatric patients) are of relatively limited size, therefore we will not need metadata analysis. Naming conventions: the project dataset identification will follow a naming based on the following convention: Data_<WPno>_<serial number of datasets>_<dataset title>. Example: Data_WP2_1_User generated content. Data sets have to be findable easily, rapidly and identically. Therefore, standard measures have to be used to identify the data sets. This can include the definition and use of naming conventions, search keywords, version numbers, metadata standards and standard data identifiers. The NicAb consortium works on a suitable list of keywords which have been carefully selected based on relevance to the research topic and expected methodologies. The data repository will host the final data. It is not a working tool. Thus, there will not be any versioning management for the data used in the project. The obtained data will not lead to metadata analysis by us.

2.2 Making data openly accessible	Patient's names and any information which could lead to their identification (address etc.) will be kept strictly confidential by the corresponding clinics. Instead, numerical coding will be used. The most useful data have been published in scientific journals. After publication of the main data, all data, apart from patients' identification, will be kept by each of the 3 partners and will be available to interested researchers upon request to any of the partners. Our data will be accessible in common "Office" files (excel, word, power point etc.). Our data will be deposited in the internal laboratory/clinic databases or institutional server with restricted access granted only to authorized personnel of each partner. Access to the non-confidential data will be individually allowed to the requesting investigators.
2.3. Making data interoperable	The data produced are interoperative. No special vocabularies and methodologies will be required for their access. We are using standard vocabulary for all data types present in our data sets, to allow inter-disciplinary interoperability.
2.4. Increase data re-use (through clarifying licences)	The data have been published in scientific journals, and some of them were submitted in parallel for patent. Our data will be made available for re-use just after their publication. The data produced and/or used in the project will be useable by third parties. Data quality is assured a. by the use of multiple internal controls and b. by their reproduction in other laboratories/clinics. The data will remain re-usable for at least 10 years.
3. Allocation of resources	The predicted costs for making our data FAIR are minimal; it will be covered by the overheads of the 3 partners. The coordinator will be responsible for data management in our project. Costs for long term preservation of the data will be minimal; will be covered by overheads of the partners' units and by income of the industrial partner (coordinator).
4. Data security	The data are securely stored in the partners' premises.
5. Ethical aspects	Data was obtained without the introduction of any bias, upon the approval and permission from the Bioethics Committees of the providing clinics and upon receiving the signed informed consent from the patients. The proper confidentiality and secure storage were ensured to protect sensitive information and access was controlled and restricted to researchers and collaborators anonymously using encryption methods.

HISTORY OF CHANGES		
Version	**Publication date**	**Change**
1.0	25.04.2021	▪ Initial version
2.0	01.03.2025	▪ Final version