COOPERATION AGREEMENT

between

1)
Klinikum rechts der Isar der Technischen Universität München
represented by its Commercial Director Marie le Claire
Department conducting the Study: Department of Neurology
Director: Univ.-Prof. Dr. Bernhard Hemmer
Project Coordinator: Prof. Dr. Paul Lingor
Ismaninger Str. 22, 81675 Munich, Germany

- hereinafter also referred to as "Partner 1"-

and

2)
Helmholtz Zentrum München
Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)
Legally represented by the management board
Legal Department
PI: Dr. Michael Menden
Ingolstädter Landstraße 1, 85764 Neuherberg, Germany

- hereinafter also referred to as "Partner 2"-

3)
ALS-Clinic St. Gallen Kantonsspital St. Gallen
Rorschacher Strasse 95, 9007 St. Gallen, Switzerland
PI: Prof. Dr. med. Markus Weber
Represented by Stefan Lichtensteiger EMBA HSG, CEO and Head of Management and Dr. med. Susanne Diener, Member of Management

- hereinafter also referred to as "Partner 3"-

4)
Institut National de la Santé et de la Recherche Médicale (INSERM)
A public scientific and technological institute having its registered office at 101 rue de Tolbiac, 75013 Paris, France, represented by its Chairman and Chief Executive Officer, Pr Didier SAMUEL, who has delegated signing authority for this agreement to the Regional Delegate of Inserm Grand-Ouest delegation, Mr Frédéric DELALEU,

Inserm U1253 "Imaging and Brain", Team Neurogenomics and Neuronal physiopathology
Faculty of Medicine
PI: Pr Philippe Corcia

- hereinafter also referred to as "Partner 4"-

5)
Research Fund of Hadassah Medical Organization
Kiryat Hadassah, POB 12000 Jerusalem Israel 9112001
PI: Dr. Yossef Lerner
Represented by Prof. Eyal Mishnai

- hereinafter also referred to as "Partner 5"-

6)
Gothenburg University
Visiting address: Medicinaregatan 11-13. 41390 Göteborg, Sweden /
Postal address: Box 430. 40530 Göteborg, Sweden
PI: Dr. Nicolas Ashton
Represented by Professor Henrik Zetterberg, Head of Department

- hereinafter also referred to as "Partner 6"-

7)
Maj Institute of Pharmacology PAS
ul. Smętna 12, 31-343 Kraków , Poland
PI: PhD Wojchiech Kuban
Represented by Professor Małgorzata Filip, PhD, Director

- hereinafter also referred to as "Partner 7"-

8)
Institute of Neuroimmunology Slovak Academy of Sciences
Dubravska 9, 845 10 Bratislava, Slovakia
PI: Assoc. Prof. Norbert Zilka
Represented by Assoc. Prof. Norbert Zilka

- hereinafter also referred to as "Partner 8"-

9)
Akdeniz University
Faculty of Medicine
Neurology Department Akdeniz University, Dumlupınar Bulvarı, Antalya,Turkey
PI: Prof. Dr. Hilmi Uysal
Represented by Vice-Rector Prof. Dr. Ayşe Gülbin Arıcı

- hereinafter also referred to as "Partner 9"-

10) **Flinders University**
Sturt Road, Bedford Park, South Australia 5042
PI: Mary-Louise Rogers
Represented by Mr Simon Brennan, Chief Research Development Officer,
Research Development & Support,

- hereinafter also referred to as "Partner 10"-

11) **Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.**
Hofgartenstraße 8, 80539 München, Germany
PI: Prof. Henning Urlaub
Deputy PI: Dr. Christof Lenz
Represented by the managing Director of the Max Planck Institute for Multidisciplinary Sciences,
Am Faßberg 11, 37077 Göttingen, Prof. Dr. Marina Rodina

- hereinafter also referred to as "Partner 11"-

- hereinafter individually and jointly referred to as the "Partner(s)" –

Whereas: The Partners, having considerable experience in the field concerned, have submitted a proposal for the project to the JPND Call for Proposals: "Linking pre-diagnosis disturbances of physiological systems to Neurodegenerative Diseases" and wish to jointly perform the Project under the framework of the EU Joint Programme – Neurodegenerative Diseases (JPND). Funding for the Project will be provided by the respective national funding organizations for partners 1-9. Partners 10-11 have agreed to collaborate with the other partners without specific funding. The Partners wish to set the terms and conditions for the implementation of the Project in addition to the provisions of the individual Grant Agreements between the respective national Funding Organisation and the respective Partner.

For the purpose of the execution of the joint project „premodiALS – A premotor disease signature for ALS" (hereinafter referred to as the "**Project**") all Partners agree as follows:

Preamble:

The Partners intend to carry out the Project together. The Partners agree to cooperate on the basis of the below-mentioned terms and conditions.

§ 0 Definitions

Words beginning with a capital letter, in singular or plural, shall have the meaning defined herein.

Agreement: means this agreement and all of its exhibits attached and its eventual further amendments.

Confidential Information: means any information and/or data, whatever its kind or form, including any written or printed documents, samples, models and/or patentable knowledge that is disclosed by one Partner, to any other Partner(s), under this Agreement and provided that the disclosing Partner has explicitly described it as "confidential", or when disclosed orally, the disclosing Partner has also described it as "confidential" at the time of disclosure and has confirmed and designated in writing within thirty (30) days at the latest as "Confidential Information" The Partners agree that Previous Proprietary Rights belonging to the other Partners is Confidential Information.

Funding Authority: Means the respective national bodies awarding funding for the Project to the Partners.

Project sponsoring Body: Means the institutions receiving funding for the Project from a national Funding Authority.

Germany, Lingor, Klinikum rechts der Isar der TU München [University clinic]
Germany, Menden, Helmholz-Zentrum München [Academia]
Switzerland, Weber, ALS-Clinic St. Gallen [Clinic]
France, Corcia, Inserm Unit U1253 Imaging and Brain [Research body]
Israel, Lerner, Research Fund of Hadassah Medical Organization [non-profit organization]
Sweden, Ashton, Gothenburg University [Academia]
Poland, Kuban, Maj Institute of Pharmacology, PAS, Kraków [Academia]
Slovakia, Zilka, Institute of Neuroimmunology Slovak Academy of Sciences [Academia]
Turkey, Uysal, Akdeniz University Faculty of Medicine, Neurology Department [University clinic]

Work Results: means any information and scientific and/or technical knowledge i.e. know-how, data, software in its source code version or in its object code version, files, plans, diagrams and figures, designs, formulae and/or any other type of information, whatever its form, as well as copy rights and other intellectual property rights pertaining to such information, which is generated by one or several Partners in the framework of this Agreement.

§ 1 Subject matter of the Agreement

(1) The subject matter of the Agreement is the cooperation of the Partners during the execution of the Project.

(2) The respective share of the work to be provided by the individual Partners as well as the timetable result from the general project plan, in particular from the overall work and time schedule including all updates, which is enclosed with this Agreement as **Exhibit 1**.

§ 2 Execution of the project work

The Partners undertake to engage in coordinated fields of work carrying out separate tasks. The Partners shall make available to each other the content of the task descriptions, timetables and all information required for the good implementation of the Project.

§ 3 Coordination

(1) The Project is coordinated by Prof. Dr. Paul Lingor from the Klinikum rechts der Isar der TU München (hereinafter referred to as "Project Coordinator"). The Project Coordinator in particular shall be in charge of coordinating the work of the individual Partners in terms of content and time. If there are any deviations from the overall work and time schedule, he will, at an early stage, inform the Partners hereof and suggest appropriate measures to overcome any problems that have occurred.

(2) If deadlines cannot be met, the Project Coordinator must be informed forthwith. He, in turn, will subsequently inform the Partners concerned.

(3) The Project Coordinator shall prepare regular meetings that are required to carry out the overall work and time schedule, send out the invitations with the enclosed agenda in due course, chair the meetings and be responsible for the preparation and dispatching of the minutes covering these meetings. Representatives of all Partners shall take part or be duly represented in these meetings. The Partners agree that no decision can modify the nature and extent of the contribution of a Party in the Project as laid down in the final version of the approved Project Application without the prior written approval of the Partner concerned; the regulations set out in Clause 10 – especially Clauses 10 (2), 10 (3), 10 (4) and Clause 10 (5) shall remain unaffected hereof.

(4) Voting rules and quorum

No Partner shall deliberate or decide validly unless two-thirds (2/3) of all Partners are present or represented (quorum). If the quorum is not reached, the Project Coordinator shall convene another ordinary meeting within 15 calendar days. If in this meeting the quorum is not reached once more, the Project Coordinator shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of all Partners are present or represented. Each Partner presented or represented in this meeting shall have one vote.
Decisions shall be taken by a majority of two-thirds (2/3) of the votes cast.

(5) Each Partner will appoint a project leader who is in charge of his tasks, and provide his address, telephone and fax numbers and e-mail address. A list of the project leaders for each Partner is attached in **Exhibit 3**.

(6) The Partners acknowledge having an obligation on each other to use best endeavours under this Agreement. Each Partner shall therefore undertake to execute its part of the work with due care and provide the other Partners with the Confidential Information that the former deems necessary to implement the Project, without prejudice to its interests.

(7) Each Partner is responsible for its obligations toward its Project sponsoring Body/national Funding Authority. The Project Coordinator will support all Partners in their reporting duties towards the Project sponsoring Bodies/national Funding Authorities and will collect the necessary reporting elements from all Partners in time. The Partners will provide the necessary reporting elements to the Coordinator in due course.

§ 4 Rights to the results/property rights

(1) Each Partner is and remains the owner of all and any intellectual property that exists at the date of entering into this Agreement, whether it is protected or not (hereinafter consistently referred to as "Previous Proprietary Rights"). The **Exhibit 2** exhaustively describes the Partners` Previous Proprietary Rights to which a right of use is granted in order to use it in the Project. **Exhibit 2** can be supplemented during the course of this Project with prior written approval of the Partner concerned.

(2) All results including all reports and documents that have been produced by the Partners during the execution of their work in performance of the Project (e.g. know-how, inventions, results protected by copyright, software) are deemed to be Work Results. If during the execution of the Project any service inventions were to be arrived at, the project leaders/Partners shall forthwith inform their employers in writing subsequently, this employer shall inform the Project Coordinator and the other Partners that a service invention has been made.

(3) Work Results that are achieved by the employees of one Partner only and do not rely on results of other Partners shall be the property of this Partner. This Partner shall also be entitled to apply for patents on his own behalf and at his own expense. He shall, however, be obliged to inform the Project Coordinator and other Partners of any such patent applications.

(4) Joint ownership

Where several Partners have jointly carried out work generating Work Results and where their respective share of the work cannot be meaningfully separated, the Partners shall jointly own such Work Results ("Joint Work Results") in proportion to their intellectual contributions that shall be determined according to the laws of the country to which this agreement shall be subject to under section 15 (5) below. The Project has the peculiarity that the results of different work packages build on each other. Therefore, a part of the Work Results is expected to be joint results of all Partners who provided data, material or information required for the generation of these results. The diagram of the workflow in the proposal (**Exhibit 1**) reflects the participation in the results.

The concerned Partners shall establish a written agreement regarding the allocation and terms of exercising that joint ownership. This agreement shall be drawn up as soon as necessary and in any event before any industrial and/or commercial exploitation of the Joint Work Results. Such agreement includes: (1) how the ownership is divided (2) the joint owners' rights and obligations concerning the exploitation of the Joint Work Results for commercial purposes (3) intellectual property protection measures, including issues related to the cost of protection (e.g. patent filing and examination fees, renewal fees, prior state-of-the-art searches, infringement actions, etc.) (4) sharing of revenues or profits (5) appointment of a joint owner leader for activating commercialization opportunities.

Where no joint ownership agreement has yet been concluded: each of the joint owners shall be entitled to use their Joint Work Results only for non-commercial research and teaching activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s).

(5) If one Partner waives his right to apply for and/or maintain a property right or a share herein, he shall first and foremost offer it to the other Partners. According to the internal intellectual property regulations of Partner 5, Partner 5 shall if Partner 5 waives his right to apply for and/or maintain a property right or share herein, first and foremost offer it to its inventors, according to its internal intellectual property regulations to the extent such applies by the Partner 5's institutional Intellectual Property Regulations and if Partner 5`s inventor/s relinquished their

right to pursue the property right, shall offer the other Partners. In the case of joint inventions, the offer shall initially be made to the joint Partners involved in the Project. The Partner shall, at the latest eight weeks after receipt of the offer, confirm in writing whether it will accept the transfer. All costs incurred from the date of the Partner accepting the offer, including the remuneration of the inventor, shall solely be borne by the Partner who accepts the invention as his. The details of the transfer will, in each single case, be subject to a separate agreement to be entered into by the concerned Partners.

§ 5 Use of the work results

(1) Each Partner acknowledges that the use of the information and the objects produced by the other Partners during the execution of the Project does not establish a right based on prior use.

(2) The use of the Joint Work Results for commercial purposes shall be determined amicably and in good faith by the Partners on the basis of an *exploitation plan*. The commercial exploitation shall be undertaken by the Partner who is best qualified if and as far as this Partner has not already been featured in the application. If several Partners may be considered for the exploitation, the Partner who has made the greatest contribution to the Joint Work Results shall be chosen. If all Partners have contributed equally, the Partner with the best chances of exploitation shall be chosen. The Partners acknowledge that the initial idea and the main concept of the Project was designed by Partner 1 and therefore Partner 1 shall be preferentially considered for being the Partner who shall undertake the commercial exploitation of the Work Results. In the event that the Partners who contributed to Joint Work Results decide unanimously against the procedure described above, the following shall apply: each of the joint owners shall be entitled to (commercially) exploit the Joint Work Results and to grant non-exclusive licenses to third parties without any right to sub-license if the other joint owners are given:

(i) at least 45 calendar days advance written notice; and
(ii) fair and reasonable compensation

(3) Any details regarding the rights of use pertaining to the commercial exploitation of the respective Work Results shall be stipulated between the Partners in an additional agreement according to the terms and conditions that are fair and reasonable and in line with customary market practice.

(4) If any work protected by copyright or any objects protected by related rights are commercially exploited, the author shall receive fair and reasonable conditions from the exploiting Partner.

(5) Each Partner has the irrevocable, gratuitous, non-exclusive and non-transferable right to use the Work Results including inventions arrived during the execution of the Project
- in the course of and during the Project and for the purpose of carrying out activities under the Project,
- after the termination of this Agreement for his own scientific purposes in the field of internal research and teaching.

As far as publications/the disclosure of Work Results to third parties are concerned, clause 8 (5) shall apply.

(6) If and as far as the use of Previous Proprietary Rights pursuant to clause 4(1) by the Partner/s is necessary for the execution of the Project, the Partners shall grant each other, for the purpose and duration of the Project, a non-exclusive, non-transferable and gratuitous right of use pertaining to their Previous Proprietary Rights insofar as the Partners concerned can freely dispose of these rights at the time of their being granted. The Previous Proprietary Rights to which a right of use is granted are listed in **Exhibit 2**.

As far as these Previous Proprietary Rights are required for the commercial exploitation of the Work Results, the exploiting Partner shall, unless third parties have conflicting rights, be granted a non-exclusive right of use based on fair and reasonable conditions and on the terms

and conditions that are in line with customary market practice. Further details will be amicably agreed between the concerned Partners in a separate written contract.

In **Exhibit 2**, the Partners have identified and agreed on the Previous Proprietary Rights for the Project and have also, where relevant, informed each other that the right of use of specific Previous Proprietary Rights is subject to legal restrictions or limits.

Anything not identified in **Exhibit 2** shall not be the object of right of use obligations regarding Previous Proprietary Rights.

§ 6 Funding

Each Partner shall bear his own costs incurred by him as part of the execution of this Agreement. Each Partner receiving funding for the Project from a national Funding Authority is required to abide with the rules and regulations applicable to such Partner's funding. The Partners agree that, for the Partner concerned, in case of a conflict of any of those national rules and regulations with the terms of this Agreement those national rules and regulations shall have precedence over the regulations of this Agreement. Should the rules applicable to several Partners contradict each other or in several respects not be in line with the terms of this Agreement, the Partners will negotiate in good faith the necessary changes of this Agreement.

There are no financial flows between the Parties.

§ 7 Other cooperation/external R&D services

(1) If one Partner cooperates with a third party on the Project, he must ensure that the other Partners shall at least have the same rights in the results achieved by this third party that they would have had if the results had been arrived at by the Partner himself.

(2) The Partner who awards a contract to a third party for the purpose of carrying out his tasks under the Project shall be responsible for this contract and shall, in particular, ensure that the contractor complies with the obligations set out in clause 8.

§ 8 Confidentiality/Publications

(1) The Partners undertake to treat confidential all Confidential Information that has been made available by a Partner ("Disclosing Partner") to the other Partners ("Recipient") under this Agreement for up to five years after the termination of or the withdrawal from this Agreement and must not disclose it to third parties.

The Recipient hereby undertakes:
- not to use Confidential Information other than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent of the Disclosing Partner;
- to ensure that internal distribution shall take place on a strict need to know basis;
- to return to the Disclosing Partner, or destroy, on request all Confidential Information that has been disclosed including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible.

(2) These obligations pursuant to clause 8 (1) do not apply to any information if it can be proven that it
- is known to the general public via publications or by similar means other than a breach of the Recipient`s confidentiality obligations; or
- becomes general knowledge by no fault of the recipient Partner; or
- has been disclosed by third parties to one Partner without any obligation of confidentiality; or
- has been known to the recipient Partner prior to it being divulged by another Partner; or
- is the result of work carried out by the employees of the recipient Partner who had no access to the confidential information; or
- is required by Recipient to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order.

(3) The Partners will also take the usual and reasonable measures vis-à-vis their employees with regard to the confidentiality of the information according to these provisions.

(4) During the Project, the Partners agree, that they will use IT infrastructure including eCRFs provided within the Project by a service provider designated by the Project Coordinator to upload their patient-related results.
The Partners will agree at the beginning of the Project on a data exchange-platform that will be used for exchange of project-relevant documents and de-identified data.

(5) The Partners agree, that the publication of Work Results will be made after the Project. If there are results that the Partners wish to publish before the end of the Project, Partners contributing results to this publication must agree.

If a joint publication has not been submitted at the latest 12 months after the end of the Project, each Partner is entitled to publish his own Work Results. The publishing Partner, however, must refer to the Project as far as this is appropriate and acknowledge the contributions of the other Partners. Prior to any publication, the respective other Partners must be informed accordingly.

(6) Any publication that contains information concerning the other Partners that is to be treated confidentially shall be subject to the prior written consent of the other Partners concerned. No Partner shall unreasonably withhold his consent. The Partner who plans to publish Work Results shall provide the Partners concerned with copies of the planned publication and may, if no objection is made within 4 weeks by the Partners, assume that the Partners do not object.

(7) The obligation to obtain the Partner's approval does not apply to Partners if they, while complying with their legal or statutory obligation to publish research findings, publish only basic scientific statements or refer to knowledge that does not endanger patent applications and hence does not include any specific information regarding other Partners that is subject to confidentiality.

(8) Nothing in this Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Partners or any of their logos or trademarks without their prior approval in text form.

§ 9 Liability/Material defects and defects of title

(1) The Partners shall perform their share of the Project by applying regular scientific diligence. The Partners understand the risk of failure inherent in research activities. Due to the research character of their work, the Partners do not warrant that a specific work result will be achieved or that the work result will be suitable for a specific purpose, can be exploited for commercial purposes or is free from the property rights of third parties. If conflicting property rights become known, the Project leaders will inform each other immediately. No duty of investigation applies.

(2) The liability for damage caused to the other Partner (e.g. loss of production) or for damage caused during the use of the Work Results/project-related information is limited to wilful intent and gross negligence.

(3) If necessary, the Partners shall help each other to defend third party claims by making the necessary statements and/or by making available the required documents. This applies in particular to litigations under patent law.

(4) During their cooperation, the Partners shall ensure that they forward any information by using the same diligence that they apply to their own matters. Neither during the time of their cooperation nor after the expiration of this Agreement, the Partners shall be liable for the accuracy and completeness of any information forwarded by them or for any damage whatsoever resulting from the use of this information.

§ 10 Term of the Cooperation Agreement

(1) This Agreement shall be effective upon being signed by all Partners at the beginning of the term of the Project on **September 1st, 2022**.

This Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Partners under this Agreement for the purposes of the completion of the Project.

The provisions relating to access rights, publication and confidentiality, for the time period mentioned herein, as well as for Previous Proprietary Rights and Work Results, liability, applicable law and settlement of disputes shall survive the expiration or termination of this Agreement.

(2) Each Partner shall be entitled to terminate this Agreement for cause by giving three months' notice.

(3) If one Partner withdraws from the Agreement according to clause 10 (2)

- his rights are limited to the Work Results that he has been informed of by the time he receives the notice of cancellation. He shall not be entitled to disclose these Work Results to third parties;
- the rights of use and access granted to the other Partners under this Agreement shall not be affected hereby;
- the tasks of the withdrawing Partner that have not been accomplished may, if the continuation of the Project is deemed to be reasonable, and subject to the consent of the remaining Partners, be taken on by a new Partner.

The obligations of the other Partners pursuant to clause 4 to 8 of this Agreement shall apply vis-à-vis the withdrawing Partner only to work results that have been arrived at prior to the receipt of the notice of cancellation and to property rights that have been applied for prior to the receipt of the notice of cancellation. The obligations of the withdrawing Partner under the above-mentioned provisions shall apply, even after his withdrawal from the Project, to all results and intellectual property rights that he arrives at due to work that he has carried out or commenced during the Project.

(4) Termination of a defaulting Partner

The Partners may decide on the total or partial termination of the Agreement by a majority of two-thirds (2/3) with regard to a Partner in the event of non-performance by such latter Partner, on one or more occasions of its obligations pursuant to this Agreement. Such termination may take place 60 calendar days after formal notice sent by the Project Leader to the defaulting Partner unless, within such period, the Defaulting Partner (i) has fulfilled its obligations or (ii) has proposed a replacement solution which is as close as possible to the objective sought. This solution must be expressly accepted by the other Partners.
The exclusion of a defaulting Partner is pronounced by the Partners.

(5) Termination related to the discontinuation of financing

Unless otherwise agreed in text form by the Partners or otherwise specified in this Agreement, the Agreement may be terminated if decided upon by a majority of two-thirds (2/3) of the Partners in regard to a Partner in the event of a decision by a national Funding Authority to no longer provide financing for the Project. Such termination may take place 60 calendar days after formal notice sent by the Project Leader.

§ 11 Acceptance of other cooperation partners joining the Project

Subject to an additional contract which is to be entered into on an individual basis and with the conditions to be agreed upon, third parties shall be entitled to become a party to this Agreement. Such new party agrees to be bound by the terms of this Agreement starting from the date indicated in the additional contract.

§ 12 Data Protection

(1) The Partners undertake to comply with all applicable Data Protection Laws and, in particular, the General Data Protection Regulation (EU) 2016/679 (hereinafter referred to as "GDPR").

(2) With regard to the personal data of the trial participants processed during the execution of this Agreement, the Partners shall jointly stipulate the purpose and means of data processing. They are therefore "Joint Controllers" in accordance with Article 26 of the GDPR. The responsibility for complying with individual obligations pursuant to the GDPR shall be based on that section 12 and the Agreement on Joint Controllership pursuant to Article 26 of the GDPR added hereunder as **Exhibit 4**.

§ 13 Material and Data Transfer

Under the framework of the Project, Data and human materials (hereinafter referred to as "Material") are going to be transferred between Partners according to **Exhibit 6**. In particular, Material that has been collected at the site of Partners 1), 3), 4), 5), 8) and 9) and at the University of Miami is going to be transferred and processed for the purpose of the Project according to **Exhibit 5**. As the University of Miami is not a party to this Agreement, Partner 1) will conclude a separate contract with the University of Miami as third party to this Agreement before Material is going to be exchanged between these two entities. Also, as this is a requirement of the funder of Partner 9), a separate MTA will be concluded with regard to the transfer of Material from Partner 9) to Partner 1); in case of conflict between the provisions of this MTA with Partner 9) and the provisions regulated in this Agreement, however, the provisions of this Agreement shall take precedence over the MTA. Likewise, in case of conflict between the provisions of the contract to be concluded with the University of Miami and the provisions regulated in this Agreement, the provisions of this Agreement shall take precedence over the contract to be concluded with the University of Miami.

The Partners agree that the Material is collected, processed and transferred only in accordance with – and also only to the extent that this has been consented by the respective trial participant – the patient information and consent which has been approved by the competent ethics committee. Unused Material can be stored at Partner 1) for 10 years from the end of the Project for the purpose of the conduct of analyses for other research for which the purpose has not yet been defined in accordance with the patient information and consent.

The providing Partners will forward the personal data and/or human materials in pseudonymized form only. The receiving Partners shall use the personal data and/or human materials solely for the Project and in compliance with applicable law, including but not limited to the provisions of the GDPR. The providing Partners confirm that the collection and transfer of the personal data and/or human materials occurs in line with applicable law. Furthermore, the providing Partners confirm that the transfer of the personal data and/or human materials as well as the processing of the personal data and/or human materials in the Project are (i) covered by a valid informed consent of the data subject obtained in accordance with applicable law and are (ii) in line with applicable conditions of an Institutional Review Board /Ethics Committee, if any.

§ 14 Export Control

The Parties shall comply with all applicable national and international laws and regulations, in particular the applicable export control regulations and sanction programs.

To facilitate Parties' compliance with applicable export control regulations, if any of the commodities, software, technology, data or information provided by the disclosing Party are classified or listed as subject to export or re-export restrictions, in the context of applicable export regulations, the disclosing Party shall inform in writing of such export control classification identification.
The Parties shall indemnify and hold the other Parties harmless from and against any and all liability, claims, proceedings, actions, fines, losses, costs, expenses and damages arising out of, connected with or resulting from the Party infringing (by act or omission) upon foreign trade law applicable to this Agreement.

§ 15 Final provisions

(1) If a provision of this Agreement is to be or become ineffective, the validity of the remaining provisions of this Agreement shall remain unaffected hereby. This provision is to be replaced retroactively with an arrangement that is legally permissible and comes closest to the content of the original provision.

(2) No Partner shall be entitled to take on any binding agreements on behalf of the other Partners without their prior express written consent.

(3) Any modifications of and amendments to this Agreement have to be made in writing and signed by the duly authorized representative(s) of the Partners. This shall also apply to a waiver of this written form requirement.

(4) Any disputes arising from this Agreement, including disputes that arise after the Agreement has expired, shall be amicably settled by the Partners involved.

(5) This Agreement shall be construed in accordance with and subject to the laws of Belgium excluding its conflict of law provisions. All disputes arising out of or in connection with this Agreement which cannot be solved amicably shall be brought before the courts of Brussels, Belgium. Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

(6) Forbearance by any of the Partners on one or more occasions from reliance on one or more provisions of this Agreement shall in no way entail waiver by the interested Partner of the possibility to rely thereon in future.

(7) This Agreement cancels and supersedes any prior written or oral agreement between the Partners and constitutes the entire agreement between the Partners with regard to the subject matter thereof.

Exhibits:

Exhibit 1 – Project Plan
Exhibit 2 – Previous Proprietary Rights (exhaustive list of Previous Proprietary Rights to which a right of use has to be granted according to § 4 (1) and § 5 (6) of the above Agreement)
Exhibit 3 – List of the Project Leader and their substitute
Exhibit 4 – Agreement on Joint Controllership pursuant to Article 26 of the GDPR
Exhibit 5 – Data and Biomaterial Flow
Exhibit 6 – Material and Data Transfer Slip

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Klinikum rechts der Isar der TU München:

Munich, 26. APR. 2023

Klinikum rechts der Isar
der Technischen Universität München
Drittmittelmanagement
Julia Schmidt
München

Marie le Claire
Commercial Director

Read and understood:

Prof. Dr. Bernhard Hemmer
Head of Department

Prof. Dr. med. Paul Lingor
Project Coordinator

Helmholtz Zentrum München:

Munich, 8.05.2023

ppa. Martina Hansen
Leitung Strategie, Programme, Resourcen

Munich, 04/05/23

ppa. Dietmar Köhl
Leitung Finanzen

Read and understood:

Dr. Michael Menden
Local Project Leader

Kantonsspital St.Gallen, ALS-Clinic:

Date: 1-Mai-2023

Name: Prof. Dr. Markus Weber
Function: Head Muskelzentrum/ALS Clinic

Date: 8.5.23

Name: Stefan Lichtensteiger
EMBA HSG
Head of Management/ Chairman of
the Executive Board

Date: 10.5.23

Name: Prof. Dr. Simon Wildermuth
Function: Member of Management

INSERM: 03 MAI 2023

Date: _____

Name: Frédéric DELALEU
Function: Regional Delegate

Frédéric DELALEU
DELEGUE REGIONAL

Date: 28/04/2023

Name: Pr Philippe Corcia
Function: Local Project Leader

Research Fund of Hadassah Medical Organization:

Jerusalem, 1 May, 2023

Prof. EYAL MISHANI
General Director
Research Fund of the
Hadassah Medical Organization

Yuval Adar
Chief Financial Officer
Hadassah Medical Organization

Prof. Eyal Mishani, CEO & Mr. Yuval Adar CFO

Read and understood:

123146

Dr. Yossef Lerner
Local Project Leader

Gothenburg University:

Date: 14/06/23

Name: Professor Henrik Zetterberg, Head of Department
Function: Legal representative

Date: 13/6/23

Name: Dr. Nicholas Ashton
Function: Local Project Leader

Maj Institute of Pharmacology PAS:

Date: 8.05.2023

Name: Professor Małgorzata Filip, PhD, Director
Function: Legal representative

Date: 08.05.2023

Name: PhD. Wojciech Kuban
Function: Local Project Leader

Institute of Neuroimmunology Slovak Academy of Sciences:

Bratislava, Nov 18, 2023

Assoc. Prof. Norbert Zilka
Legal Representative

Read and understood:

Assoc. Prof. Norbert Zilka
Local Project Leader

Akdeniz University Faculty of Medicine
Neurology Department:

Antalya, _____

_____
Prof. Dr. Murat Turhan
Akdeniz University Vice-Rector

Read and understood:

_____
Prof. Dr. Hilmi Uysal
Local Project Leader

Flinders University:

Bedford Park, _____

Mr. Simon Brennan
Legal representative

Read and understood:

Assoc. Prof. Mary-Louise Rogers
Local Project Leader

Max Planck Institute for Multidisciplinary Sciences:

Göttingen, 22.05.2023

Prof. Holger Stark
- Managing Director –

MAX PLANCK INSTITUTE
FOR MULTIDISCIPLINARY
SCIENCES
Managing Director
Am Fassberg 11, 37077 Goettingen
+49 551 201-2010 gd@mpinat.mpg.de

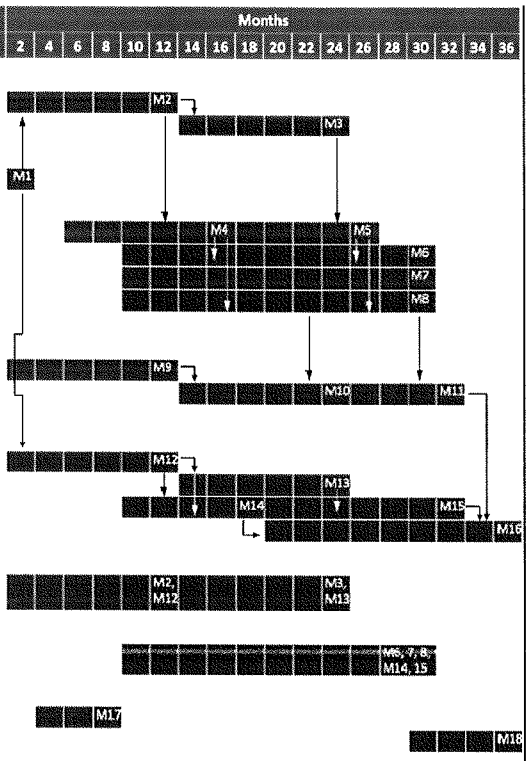
Read and understood:

MAX PLANCK INSTITUTE
FOR MULTIDISCIPLINARY
SCIENCES
Prof. Dr. Henning Urlaub
Am Fassberg 11, 37077 Goettingen, Germany
+49 551 201-1060
henning.urlaub@mpinat.mpg.de

Prof. Henning Urlaub
Local Project Leader

Exhibit 1 – Project Plan

Work packages	Partners involved
WP1: Recruitment of PGMC cohort	
Recruitment of the PGMC cohort, base-line visit V0	LI,WE,LE,CO,BE
Follow-up visit V1 (=V0+12 months) PGMC cohort	LI,WE,LE,CO
WP2: Development of questionnaire	
Questionnaire development based on EARLY-ALS	LI,ME
WP3: Characterization of PGMC molecular landscape	
Preparation of samples for analyses according to SOP	LI
Analysis of tear fluid and CSF samples (proteomics, SIMOA)	AS,LZ
Analysis of blood samples (proteomics)	KU
Analysis of urine samples (ELISA)	RO
WP4: Bioinformatic data integration, fingerprint generation and validation	
Integration of available data (EARLY-ALS, CSF and TF-omics)	ME, LI
Building a PGMC fingerprint	ME, LI
WP5: Recruitment of independent validation cohort, validation of PGMC fingerprint	
Recruitment of validation cohort, base-line visit V0	LI,WE,LE,CO
Follow-up visit V1 (=V0+12 months) validation cohort	LI,WE,LE,CO
Analysis of biosamples from validation cohort	AS,LZ,KU,RO
Validation of PGMC fingerprint in independent cohort	ME
WP6: Supportive recruitment of PGMC and validation cohort	
Recruitment of PGMC and validation cohorts in accordance to WP1 and WP5	UY, ZI
WP7: Metabolomic analyses	
Metabolomic analyses of plasma, urine and CSF samples	ZI
Preparation of manuscripts	
Evaluation and adaptation of the EARLY-ALS trial data	ALL
PGMC fingerprint and validation	ALL



Partners: AS: Ashton, BE: Benatar, CO: Corcia, KU: Kuban, LI: Lingor, LE: Lerner, LZ: Lenz, ME: Menden, RO: Rogers, UY: Uysal, WE: Weber, ZI: Zilka

Milestones:

M1 – Questionnaire developped based on EARLY-ALS
M2 – PGMC base-line visits completed
M3 – PGMC follow-up visits completed
M4 – all samples of PGMC base-line visits prepared
M5 – all samples of PGMC follow-up visits prepared
M6 – all PGMC tear fluid and CSF samples analyzed
M7 – all PGMC blood samples analyzed
M8 – all PGMC urine samples analyzed
M9 – available data integrated
M10 – PGMC fingerprint of base-line data established
M11 – PGMC fingerprint completed
M12 – validation cohort base-line visits completed
M13 – validation follow-ups completed
M14 – validation cohort base-line analyzed
M15 – validation cohort follow-up analyzed
M16 – validation cohort fingerprint established
M17 – manuscript on EARL—ALS prepared
M18 – manuscript on fingerprints of PGMC and validation cohort completed

Exhibit 2 – Previous Proprietary Rights (exhaustive list of Previous Proprietary Rights to which a right of use has to be granted according to § 4 (1) and § 5 (6) of the above Agreement)

Lingor/TUM:

- preliminary data from the EARLY-ALS trial and respective questionnaires
- preliminary data from the MAXOMOD project and any SOPs and their adaptations used in MAXOMOD

Partner 5/Research Fund of Haddasah Medical Organization:

Research Fund of Hadassah Medical Organization is responsible for recruiting patients experiencing pre-diagnosis disturbances of physiological systems into an early stage ALS Clinical trial delineated as integral part of the Project.

Exhibit 3 – List of the Project Leader and their substitute

Name of the Partner	Project Leader	Substitute
Klinikum rechts der Isar der TU München	Paul LINGOR	Dr. Lucas CALDI GOMES
Helmholtz Zentrum München	Michael MENDEN	Mrs Ana GALHOZ
ALS-Clinic St. Gallen	Markus WEBER	PD Dr. Christoph NEUWIRTH
Gothenburg University	Nicholas ASHTON	Prof. Henrik ZETTERBERG
Inserm Unit 1253, Tours	Philippe CORCIA	Dr. Anne-Sophie PIEGAY, a.piegay@chu-tours.fr
Research Fund of Hadassah Medical Organisation	Dr. Yossi LERNER	Prof. Marc GOTKINE
Maj Institute of Pharmacology, PAS	PhD Wojciech KUBAN	PhD Przemek Mielczarek
Institute of Neuroimmunology	Norbert ZILKA	Petr NOVAK
Akdeniz University Neurology Department	Hilmi UYSAL	Dr. Abrir ALAAMEL
Flinders University	Mary-Louise ROGERS	Dr. Stephanie SHEPHEARD
Max Planck Institute for Multidisciplinary Sciences	Henning URLAUB	Christof LENZ

Exhibit 4

Agreement on Joint Controllership pursuant to Article 26 of the GDPR

between

Klinikum rechts der Isar der Technischen Universität München

- in the following „**MRI**" or „**Partner 1)**" -

and

Helmholtz Zentrum München

- in the following „**Helmholtz**" or „**Partner 2)**"

and

ALS-Clinic St. Gallen

- in the following „**ALS-Clinic**" or „**Partner 3)**"

and

INSERM

- in the following „**INSERM**" or „**Partner 4)**"

and

Research Fund of Hadassah Medical Organization

- in the following „**Hadassah Medical Organization**" or „**Partner 5)**"

and

Gothenburg University

- in the following „**Gothenburg University**" or „**Partner 6)**"

and

Maj Institute of Pharmacology PAS

- in the following „**Maj Institute**" or „**Partner 7)**"

and

Institute of Neuroimmunology Slovak Academy of Sciences

- in the following „**Slovak Academy of Sciences**" or „**Partner 8)**"

and

Akdeniz University

- in the following „**Akdeniz University**" or „**Partner 9)**"

and

Flinders University

- in the following „**Flinders University**" or „**Partner 10)**"

and

Max Planck Institute for Multidisciplinary Sciences

- in the following „**Max Planck Institute for Multidisciplinary Sciences**" or „**Partner 11)**"

- individually and jointly also referred to as „**Partners**" in the following –

-

1. Subject Matter of the Agreement

1.1 This Agreement constitutes an Agreement according to Art. 26 of the GDPR. This Agreement, in addition to the above Clause 12, regulates the processing of personal data under the joint controllership of the Partners.

1.2 In the context of the cooperation of the Partners in accordance with the Cooperation Agreement on the joint research project „premodiALS – A premotor disease signature for ALS" (hereinafter referred to as „Research Project") with effective date as of September 1st, 2022 (hereinafter referred to as „Main Contract") according to Clause 12 (2) of the Main Contract above, the Partners jointly determine the purposes and means of the processing activities of certain personal data (hereinafter referred to as "data" or "data processing") described in more detail in this Agreement including its Annexes. Therefore, the Partners act as Joint Data Controllers according to Art. 26 of the GDPR.

1.3 This Agreement regulates the rights and obligations of the Partners under data protection law with regard to this data processing and specifies in particular the allocation and attribution of the tasks and obligations under applicable data protection law (in particular the GDPR) between the Partners.

1.4 For data processing activities for which there is no joint determination of purposes and means, each Partner is regarded as independent controller within the meaning of Art. 4 No. 7 of the GDPR.

2. Subject Matter, Purpose, Means and Scope of the Data Processing/Data Flow

2.1 The subject matter of the data processing is the collection, storage and processing of demographic and health data of trial participants as well as data on their Material

within the scope of the Research Project, as described in the Main Contract but also depicted in detail in **Exhibit 5**.

2.2 For the purpose of the implementation and for the duration of the cooperation (as specified in the Main Contract), Partners 1, 3, 4, 5, 8, 9 as well as the University of Miami, which will be bound by way of a separate contract - which are those Partners of the Main Contract and third parties (University of Miami) who are recruiting patients/trial participants for the Research Project at their Institution – collect and store data (including personal data of the trial participants) as well as corresponding Material as depicted in clause 2.1 of the Agreement; Partners 1, 3, 4, 5, 8, 9 and the University of Miami then assign a pseudonym to the personal data as well as to the Material and import these pseudonymised data via eCRF via an interface into a database operated by Partner 1 in Munich, Germany, EU. The Material is provided by these Partners 3, 4, 5, 8 and 9 in a pseudonymized way to Partner 1. Partner 1 then redistributes the Material (that was provided by Partners 3, 4, 5, 8 and 9 and the University of Miami) to Partners 6, 7, 8, 10 and 11 which are all „non-patient-recruiting Partners" for the purpose of analysing the samples. These Partners 6, 7, 8 and 10 then provide analysis results of the Material together with the associated pseudonym to Partner 2, who will provide a suitable data platform. Partner 2 will carry out the central integration of the data provided by all Partners.

The data processing shall be carried out in accordance with the specifications on purposes, means and scope contained in Annex 1 to this Agreement (hereinafter also referred to as „**Annex 1**"). It relates to the type of data and the categories of data subjects specified in **Annex 1**.

3. Phases of Data Processing/Data Protection Responsibilities

3.1 Responsibilities with regard to data processing are divided between the Partners according to phases of data processing as described in **Annex 1** (hereinafter referred to as "effective area(s)").

3.2 The data shall be stored in a structured, common and machine-readable format.

3.3 The Partners shall observe the principle of data minimization within the meaning of Art. 5 (1) c of the GDPR.

3.4 The other Partner must be informed before any deletion of data; he/she may object to the deletion for a justified reason, for example if he/she has a legal obligation to retain the data or if he/she has an overriding right to the storage of the data. The Partners shall draw up a protocol on the deletion or destruction of the data.

3.5 The Partners shall themselves ensure that they are able to comply with all statutory retention obligations existing in relation to the data. To this end, they shall (without prejudice to corresponding provisions in this Agreement) take appropriate data protection precautions. This applies in particular in the event of a termination of the cooperation.

3.6 Notwithstanding the provisions of Clause 3.1 regarding the responsibilities assigned to each of them individually for specific phases of the data processing, the Partners shall be jointly responsible for the lawfulness of all data processing.

4. Information of Data Subjects

4.1. Each Partner who collects personal data of trial participants – i.e. Partners 1, 3, 4, 5, 8, 9 – shall be responsible in this respect for fulfilling the information obligations pursuant to Art. 13 and 14 GDPR. Data subjects shall be provided with the required information free of charge in a precise, transparent, comprehensible and easily accessible form in clear and simple language.

4.2. Each Partner who collects personal data of trial participants – i.e. Partners 1, 3, 4, 5, 8, 9 – shall himself be responsible for the accuracy and correctness of the data protection information and declaration of consent in line with the requirements of Article 12 et seq. of the GDPR. The data protection information and declaration of consent must, among other things, contain the following details:

a. Information that the respective Partners are joint Controllers pursuant to Article 26 of the GDPR as well as the essence of this Agreement pursuant to Article 26(2) sentence 2 of the GDPR;

b. the contact data of the respective Controllers;

c. the contact data of the data protection officer of the respective Controller;

d. the purpose for which the personal data is meant to be processed as well as the legal basis for the processing;

e. where necessary the recipients or categories of recipients of the personal data;

f. the time during which the personal data is meant to be stored;

g. the existence of the trial participants' right to be informed of any personal data referring to him/her as well as their right to have the data rectified or erased or the processing restricted or their right to object to the processing as well as their right to data portability;

h. the existence of a right to withdraw consent at any time without such affecting the lawfulness of the processing based on consent before its withdrawal;

i. the existence of a right to lodge a complaint with a supervisory authority.

4.3. The respective Partners 1, 3, 4, 5, 8, 9 are each responsible for properly informing their trial participants about the processing of their personal data in connection with the Research Project.

4.4 The respective Partners 1, 3, 4, 5, 8, 9 shall also be responsible for ensuring that their respective trial participant gives his/her written consent to the data processing before the processing of his/her personal data begins. The original of the signed data protection consent form is kept together with the other study materials at the study site of the respective Partner 1, 3, 4, 5, 8, 9.

4.5 The Partners undertake, within the scope of their spheres of activity, to make the essential contents of this Agreement available to the data subjects in accordance with Art. 26 (2) sentence 2 of the GDPR.

5. Fulfilment of other rights of Data Subjects

5.1 The Partners 1, 3, 4, 5, 8, 9 are responsible for processing and responding to requests from data subjects to exercise their rights under Art. 15 et seq. GDPR ("data subject rights"). The respective other Partner shall provide the Partner providing the information with the necessary information from its effective area of activity without delay at the latter's request.

5.2 If a data subject approaches one of the aforementioned Partners to exercise his/her data subject rights, the Partners undertake to forward this request to the other Partner without delay, insofar as the latter is obliged to grant the data subject rights under this Agreement.

5.3 Notwithstanding Clause 5.1 of this Agreement, the Partners agree that data subjects may contact any of the Partners to exercise their respective data subject rights.

5.4 In the event of a data subject`s request for erasure, Clause 3.5 of this Agreement shall apply accordingly.

6. Security of Data Processing

Within their respective effective area of activity, the Partners 1, 3, 4, 5, 8, 9 shall implement and maintain technical and organisational measures to ensure adequate protection of the data which – also with regard to any special categories of personal data – shall at all times at least meet the requirements laid down in Art. 32 GDPR. In doing so, they shall ensure that the rights of the data subjects, in particular pursuant to Art. 12 to 22 GDPR, can be ensured at all times within the statutory time limits.

7. Data Processing in Third Countries

For the Research Project, personal data (in a double-pseudonymized way) of trial participants are being transferred to third countries outside the European Union without adequacy decision according to Art. 45 (3) of the GDPR, namely to Australia (Partner 10).

In order to ensure an adequate level of data protection for this data transfer to third countries according to Art. 44 et seq GDPR it has to be ensured that in the context of the data protection information and the informed consent form, it will inform trial participants that, if personal data is transferred to the USA and/or to third countries without an adequacy decision it is not possible to ensure an adequate level of data protection and that such data transfers entail special risks and that, therefore, personal data can only be transferred to the USA and/or to third countries without an adequacy decision if the trial participant explicitly consents to the data transfer in accordance with Art. 49 (1) a) of the GDPR despite the absence of an adequate level of protection and the associated risks. The necessary consent has to be obtained from the trial participant in accordance with Art. 49 (1) a) of the GDPR within the framework of data protection information and declaration of consent.

8. Processing on behalf of a Controller (Art. 28 GDPR)

8.1 If processors are used to fulfil the purpose of this Agreement, the Partners undertake to conclude a contract in line with Art. 28 of the GDPR. The Partners shall inform one another in good time of any intended change with regard to the use or replacement of processors used as sub-contractors. They shall only use such sub-contractors who undertake to fulfil the requirements of the applicable data protection laws and this Agreement.

8.2 Services contracted with third parties performing ancillary services to support the Clinical Trial (e.g. telecommunication and maintenance work) shall, hereunder, not be deemed to be services by processors under this Agreement. To ensure the protection and security of the personal data, the Partners shall, however, even with regard to such ancillary services, undertake to enter into appropriate contractual arrangements and carry out the necessary control measures.

9. Duties of information resulting from data protection breaches

9.1 The Partners shall inform each other without undue delay, at the latest within 36 hours after having become aware of it, of any breaches of the protection of personal data within the scope of this Agreement within the meaning of Art. 4 No. 12 of the GDPR (hereinafter also referred to as "Data Breach(es)").

9.2 In their respective effective areas of activity all Partners are obliged to report and notify the supervisory authority and the persons affected by a data breach in accordance with Art. 33 and 34 of the GDPR.

9.3 The Partners shall cooperate in a notification pursuant to Art. 33 and 34 of the GDPR as well as in a clarification and elimination of data breaches within the scope of what is necessary and reasonable; in particular they shall provide each other with all relevant information in this context without undue delay.

9.4 Before a Partner makes a notification pursuant to Clause 9.2 of this Agreement to a supervisory authority or a data subject, it shall coordinate the procedure with the other Partner to the extent possible.

9.5 The data protection contact persons of the respective Partners are listed in **Annex 2** to this Agreement (hereinafter also referred to as „**Annex 2**").

10. Other joint and mutual obligations

10.1 The Partners are obliged to appoint a competent and reliable data protection officer in accordance with Art. 37 of the GDPR or other applicable data protection laws, if and as long as the legal requirements for an obligation to appoint are met. The contact details of the data protection officer are listed in **Annex 2**.

10.2 The Partners shall ensure that all persons involved in data processing are obliged to maintain confidentiality with regard to the data and have been duly informed about the applicable provisions of the GDPR.

10.3 The Partners shall include the data processing in their respective records of processing register pursuant to Art. 30 (1) of the GDPR and note it there as a processing under joint controllership.

10.4 The Partners shall inform each other immediately and in full if errors or irregularities in the data processing or violations of provisions of this Agreement or applicable data protection law (in particular the GDPR) are identified.

10.5 The Partners shall each appoint a permanent contact person and his/her deputy for all questions arising in connection with this Agreement or the data processing. The current contact persons and deputies are defined in **Annex 2**. A change in the person of the contact person or the deputies shall be notified to the other Partner in writing without delay.

10.6 The Partners shall support each other in complying with the stipulations agreed in this Agreement as well as with the applicable statutory data protection provisions (in particular the GDPR) within the scope of what is necessary and reasonable; this includes in particular:

- the obligation to support the respective other partner in establishing and maintaining appropriate technical and organisational measures in accordance with section 6 of this Agreement;

- the obligation to support each other in any required data protection impact assessment and any consultation obligations of the competent supervisory authority pursuant to Art. 35, 36 of the GDPR; in this case, the Partners shall mutually determine who shall take the lead; the other Partners shall be appropriately involved;

- the obligation to assist each other in the establishment and maintenance of the records of processing.

10.7 The Partners undertake to document all facts, effects and measures taken in connection with this Agreement or the data processing to the extent required.

11. Cooperation with supervisory authorities

11.1 The Partners shall notify each other without undue delay if they are approached by a data protection supervisory authority in relation with this Agreement, the cooperation or the data processing.

11.2 The Partners agree that requests by competent data protection supervisory authorities must be complied with. In particular, any information requested must be provided and opportunities for inspection (also on site) must be granted. In this context, the Partners shall grant the competent data protection supervisory authorities the necessary rights of access, information and inspection.

11.3 To the extent possible, the Partners will consult with each other before complying with any requests from competent data protection supervisory authorities or before disclosing information in connection with this Agreement, the cooperation or the data processing, to competent data protection supervisory authorities.

12. Liability

12.1 Irrespective of the provisions set out hereunder, the Partners shall, vis-à-vis the Partners concerned, be externally and jointly liable for any loss/damage caused by personal data processing that does not comply with the GDPR (see Art. 82(4) of the GDPR).

12.2 If one of the Partners suffers a loss/damage due to the breach of a data protection regulation by the respective other Partner, the Partner breaching the regulation shall be obliged to compensate the injured Partner for the loss/damage suffered.

13. Miscellaneous

13.1 This Agreement shall enter into force on the effective date of the Main Contract and may only be terminated for cause. Cause may, in particular, be a serious or continuous breach of the data protection regulations or the provisions of this Agreement. This Agreement shall continue to apply beyond the end of the Main Contract until the processing of personal data due to the Main Contract is no longer required.

13.2 In the event of any inconsistency between this Agreement and the Main Contract, the provisions of this Agreement shall prevail with regard to data processing. Insofar as this Agreement does not contain any regulation, those of the Main Contract shall apply.

Annex 1)

Purpose, Means and Scope of Data Processing:

- **Patient recruiting Partners = Trial Centers:** Partner 1 (MRI), Partner 3 (ALS-Clinic St. Gallen), Partner 4 (INSERM), Partner 5 (Hadassah Medical Organization), Partner 8(Institute of Neuroimmunology Slovak Academy of Sciences), Partner 9 (Akdeniz University);

  → **Partner 8 has a "double-role" as Trial Center and Analytical Center:** Reference to Partner 8 does not only entail contributions of Partner 8 (Institute of Neuroimmunology Slovak Academy of Sciences) itself but also contributions of Jessenius Faculty of Medicine/Commenius University as Trial Centre who will not be a Party to this Agreement; as regards the contributions of Commenius University, Partner 8 and Commenius University will conclude a separate agreement in order to reflect them accordingly.

- **Non-patient recruiting Partners = Analytical Centers:** Partner 2 (Helmholtz), Partner 7 (Maj Institute of Pharmacology PAS), Partner 8 (Institute of Neuroimmunology Slovak Academy of Sciences), Partner 6 (Gothenburg University), Partner 10 (Flinders University), Partner 11 (Max Planck Institute for Multidisciplinary Sciences)

Stage of data Processing	**Categories of data**	**Categories of concerned persons**	**Legal basis for the processing of the data (GDPR)**	**Main controller for the processing in question**
Collection of data from data subject	Identifying data, pseudonyms, health data	Trial participants	Art. 6 (1) point a Art. 9 (2) point a	All patient recruiting Partners
Storing of data in the data base	Pseudonyms, health data	Trial participants	Art. 6 (1) point a Art. 9 (2) point a	Partner 1) for storing the data in the server provided by Partner 1); Partner 2) for storing the data in the data server for data integration located at Partner 2)

Modification and deletion of data	Pseudonyms, health data	Trial participants	Art. 6 (1) point a Art. 9 (2) point a	All patient recruiting Partners
Evaluation or use of the data for analysis purposes	Pseudonyms, health data	Trial participants	Art. 6 (1) point a Art. 9 (2) point a	Non-patient recruiting Partners
Engaging and scrutinising processors and their subprocessors (Art. 28)	Pseudonyms, health data	Trial participants	Art. 6 (1) point a Art. 9 (2) point a	Each Partner for the contract processor he is engaging
Designing and providing the data protection information and declaration of consent for trial trial participants	n.a.	n.a.	n.a.	Respective patient recruiting Partner for its own site
Collection of the data protection information and declaration from the trial participants	Identifying data	Trial participants	Art. 6 (1) point a	Respective patient recruiting partner for its own site
Storing the original documents for information purposes and consent from the trial participant as required by data protection regulations	Identifying data	Trial participants	Art. 6 (1) point a	Respective patient recruiting partner

Processing enquiries for information (Art. 15), Processing enquiries concerning rectifications (Art. 16), processing enquiries concerning data erasure (Art. 17), processing enquiries concerning the restriction of processing (Art. 18)	Identifying data, pseudonyms, health data	Trial participants	Art. 6 (1) point a Art. 9 (2) point a Art. 15 Art. 34 (1), (4) Art. 17, 18	All Partners

Annex 2) Contact Data for Partners:

Contact Data for Klinikum rechts der Isar der Technischen Universität München (Partner 1):

Contact Data	**Data Protection Department** Address: Ismaninger Straße 22, 81675 München Germany E-Mail address: datenschutz@mri.tum.de Telephone number: +49 (0)89/4140 - 0
Contact according to Clause 10.5	Data Protection Department
substitute contact person according to Clause 10.5	Prof. Dr. Paul Lingor Ismaninger Straße 22, 81675 München Germany E-Mail address: paul.lingor@mri.tum.de Telephone number: +49 (0)89/4140-8257

Contact Data for Helmholtz Zentrum München (Partner 2):

Contact Data	**Data Protection Officer** Address: Ingolstädter Landstr. 1, 85764 Neuherberg Germany E-Mail address: datenschutz@helmholtz-munich.de Telephone number: +49 (0)89/3187-0 **Data Protection Management**

	Address: as above E-Mail address: dataprotectionmanagement@helmholtz-munich.de
Contact according to Clause 10.5	Data Protection Management

Contact Data for Partner 3) (ALS-Clinic St. Gallen):

Contact Data	**Data Protection Officer** Address: Rorschacher Strasse 97, 9007 St.Gallen, Switzerland E-Mail address: bianka.doerr@kssg.ch Telephone number: +41 (0) 71 494 62 94

Contact Data for Partner 4) (INSERM):

Name: **Adèle LEROY-LUSSON**
Gestionnaire des Ressources Externes - Pôle Management des Contrats
Address: Inserm, Délégation régionale Grand Ouest
Atlantica Bâtiment K, 24 Boulevard Vincent Gâche, 44200 NANTES
Tél. +33 (0)2 40 35 86 79 |
Email: adele.leroy-lusson@inserm.fr

Contact Data for Partner 5) (Research Fund of Hadassah Medical Organization):

Data Protection Officer:

Name: Liza Gabai
address: Kiryat Hadassah POB 12000 Jeruslem Israel 9112001
email: lizag@hadassah.org.il
Tel: +972 50 8946761
Name: Dr. Yossef Lerner
address: Kiryat Hadassah POB 12000 Jeruslem Israel 9112001
email: lernery@hadassah.org.il
Tel: +972 54 5950413

Contact Data for Partner 6) (Gothenburg University):

Name: Dr. Nicholas Ashton
Address: Dept. Psychiatry and Neurochemistry

Sahlgrenska Academy at Gothenburg University

Mölndal Hospital, Hus V3, 43180 Mölndal, Sweden

e-mail: nicholas.ashton@gu.se

Contact Data for Partner 7) (Maj Institute):

Name: PhD. Wojciech Kuban
Address: Maj Institute of Pharmacology, PAS
ul. Smętna 12,
31-343 Kraków
e-mail: kuban@if-pan.krakow.pl
phone: +48 12 6623314

Contact Data for Partner 8) (Slovak Academy of Sciences):

Name: Assoc. Prof. Norbert Zilka
Address: Institute of Neuroimmunology Slovak Academy of Sciences
Dubravska 9, 845 10 Bratislava, Slovakia
e-mail: norbert.zilka@savba.sk

Contact Data for Partner 9) (Akdeniz University):

Name: Assoc. Prof. Dr. Uğur Bilge

Address: Medical School

Department of Basic Medical Sciences

Department of Biostatistics and Medical Informatics

E-mail: ubilge@akdeniz.edu.tr

Office phone: +90 242 249 6929

Contact Data for Partner 10) (Flinders University):

Name: Flinders University

ABN: 65 542 596 200

Address: Sturt Road, Bedford Park, South Australia 5042

Email: research.contracts@flinders.edu.au

Attention: Director of Research, Development and Support

Contact Data for Partner 11) (Max-Planck-Institute for Multidisciplinary Sciences):

Name: Prof. Dr. Henning Urlaub

Address: Am Fassberg 11, 37077 Göttingen,

phone: +49 551 2011060

e-mail: henning.urlaub@mpinat.mpg.de

Exhibit 5: Data and Biomaterial Flow

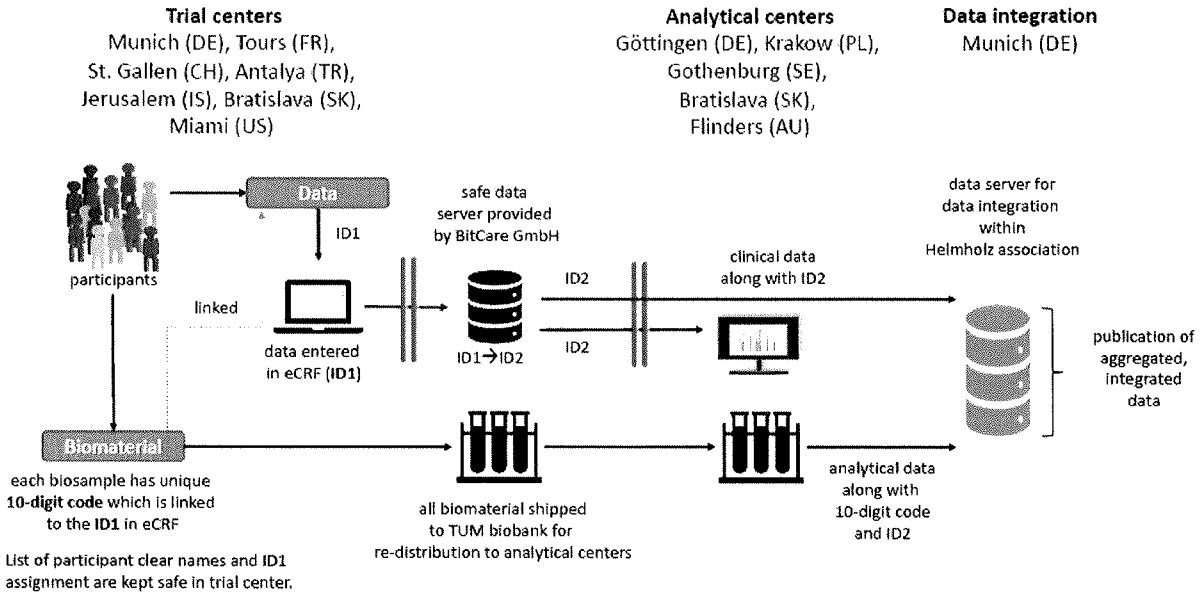


Exhibit 6: Material and Data Transfer Slip

As part of the PREMODIALS Consortium Agreement entered into force on September, 1st, 2022 and signed between:

- **Klinikum rechts der Isar der Technischen Universität München**
- **Helmholtz Zentrum München**
- **ALS-Clinic St. Gallen Kantonsspital St. Gallen**
- **Institut National de la Santé et de la Recherche Médicale (INSERM)**
- **Research Fund of Hadassah Medical Organization**
- **Gothenburg University**
- **Maj Institute of Pharmacology PAS**
- **Institute of Neuroimmunology Slovak Academy of Sciences**
- **Akdeniz University**
- **Flinders University**
- **Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.**

The Issuing Party (hereinafter defined) agrees to the transfer of the Material -described below- to the Recipient Party (hereinafter defined) to carry out the Project according to the terms and conditions of the Agreement referred to above.

Material:	Nature and characteristics: Biological sample (Serum, Plasma, Urine, CSF and Tear fluid) Quantity (for the Samples): Shipment 1: 12x 0.5 ml of Plasma visite 1 + 12x 0.5 ml of Plasma visite 2 12x 0.5 ml of Serum visite 1 + 12x 0.5 ml of Serum visite 2 8x 0.5 ml of Urine visite 1 + 8x 0.5 ml of Urine visite 2 14x 0.5 ml of CSF visite 1 + 14x 0.5 ml of CSF visite 2 2 stripes of Tear fluid visite 1 + 2 stripes of tear fluid visite 2 Shipment2: Same samples as above. 1) 2-3 tubes of CSF, serum and plasma visite 1 + 2-3 tubes of CSF, serum and plasma visite 2: 2) 2-3 tubes of CSF, serum and plasma visite 1 + 2-3 tubes of CSF, serum and plasma visite 2. 3) 2-3 tubes of CSF, serum and plasma visite 1 + 2-3 tubes of CSF, serum and plasma visite 2. 4) 2-3 tubes of Urine visite 1 + 2-3 tubes of Urine visite 2 5) Tear fluid stripes from visit 1 and 2 Samples preparation before conditioning: everything is prepared according to SOP and described in the Sample Collection Instruction sent to every partners Conditioning (tube, bag, etc. for the Samples): Tubes containing biomaterials are stored in a 96 wells micronic racks containing all 0.75 ml tubes. Format (for the Data): Refer top § 8 Confidentiality/Publications (4)
Transport of the Material:	All biomaterials will be sent with "GO Logistic", and tracking number will be generated for each individual shipment.

Issuing Party:	- name - address - contact information Shipment 1: Partner 3, Partner 4, Partner 5, Partner 8, Partner 9 (see info p.1-2 and Annex 2: Contact Data for Partners) Shipment 2: Partner 1: Prof. Dr. Paul Lingor (see info p.1 and Annex 2: Contact Data for Partners)
Contact information of the scientific sending the Material:	Name: Email: Tel: Fax: Shipment 1: Name: Partner 3: Markus Weber Address: Kantonsspital St.Gallen, ALS Clinic, z.H. Susanne Wäger, Muskelzentrum/ALS Clinic, Rorschacher Strasse 95 / Haus 33A / 1.Stock, 9007 St. Gallen, Switzerland Email: markus.weber@kssg.ch Tel: +41 071 494 35 81 Name: Partner 4: Pr CORCIA Philippe Address: Service de neurologie-Centre de référence SLA CHRU de Tours- hôpital Bretonneau 2 Boulevard Tonnelle, 37000 Tours FRANCE Email: philippe.corcia@univ-tours.fr Tel: +33 (0)2 18 37 08 09 Name: Partner 5: Dr. Yossi Lerner Address: Hadassah University Hospital-Ein Kerem Neuromuscular and ALS Clinic Department of Neurology, 6 floor room 3 in the old building Kalman Ya'akov Man St Jerusalem, Israel Email: yosef.m.lerner@gmail.com Tel: +972 54 5950413 Name: Partner 8: dr Norbert Zilka Address: Biomedical Center Martin Laboratory of Proteomics and Mitochondriopathies Jessenius Faculty of Medicine in Martin Mala Hora 4D, 2nd floor 03601 Martin Slovak Republic Email: norbert.zilka@savba.sk Tel: +421 2 32296111

	Name: Partner 9: Prof. Dr. Hilmi Uysal Address: Akdeniz Üniversitesi Hastanesi B Blok Kat 2 Nöroloji Bölümü Kampus/Antalya TURKEY Email: hilmi.uysal@gmail.com Tel: +09 5332385605 Name: third party (University of Miami): Dr. Michael Benatar Address: Email: mbenatar@med.miami.edu Tel: Shipment 2: Name: Partner 1: Prof. Dr. Paul Lingor (see info p.1 and Annex 2: Contact Data for Partners) Address: Klinikum rechts der Isar an der TU München Neuro-Kopf-Zentrum Klinik für Neurologie 2. Stock Neuro-Forschung, Raum 60.2.1, Ismaninger Strasse 22, 81675 Munich, Germany. Email: paul.lingor@tum.de Tel: **+49 89 4140 8257**
Recipient Party:	- name - address - contact information Shipment 1: Partner 1 (see info p.1 and Annex 2: Contact Data for Partners) Shipment 2: 1) Partner 6 (see info p.1-2 and Annex 2: Contact Data for Partners) 2) Partner 7 (see info p.1-2 and Annex 2: Contact Data for Partners) 3) Partner 8 (see info p.1-2 and Annex 2: Contact Data for Partners) 4) Partner 10 (see info p.1-2 and Annex 2: Contact Data for Partners)
Delivery address:	Address: Email: Tel: Fax: Shipment 1:

	Name: Partner 1: Prof. Dr. Paul Lingor (see info p.1 and Annex 2: Contact Data for Partners) Klinikum rechts der Isar an der TU München Neuro-Kopf-Zentrum Klinik für Neurologie 2. Stock Neuro-Forschung, Raum 60.2.1, Ismaniger Strasse 22, 81675 Munich, Germany. Email: paul.lingor@tum.de Tel: +49 89 4140 8257 Shipment 2: 1) Name: Partner 6: Dr. Nicholas Ashton Address: Dept. Psychiatry and Neurochemistry Sahlgrenska Academy at Gothenburg University Mölndal Hospital, Hus V3, 43180 Mölndal, Sweden e-mail: nicholas.ashton@gu.se Tel: +46738011987 2) Name: Partner 7: PhD. Wojciech Kuban Address: Maj Institute of Pharmacology, PAS Department of Pharmacokinetics and Drug Metabolism ul. Smętna 12, 31-343 Kraków POLAND Email: kuban@if-pan.krakow.pl Tel: +48 12 6623314 3) Name: Partner 8: Assoc. Prof. Norbert Zilka Address: Institute of Neuroimmunology Slovak Academy of Sciences Dubravska 9, 845 10 Bratislava Slovakia Email: norbert.zilka@savba.sk Tel: +421 2 32296111 4) Name: Partner 10: Assoc Professor Mary-Louise Rogers Address: Flinders University, College of medicine & Public Health, MND&NR Lab C/- Flinders Medical Centre Room 6E140/409/ Office: 6E116 Flinders Drive, Bedford Park, 5042 South Australia Australia Email: mary-louise.rogers@flinders.edu.au Tel: 61 8 82045320 // 61 400152991 5) Name: Partner 11: Dr. Christof Lenz Address: Universitaetsmedizin Goettingen Institut fuer Klinische Chemie Att. Christof Lenz / Lisa Neuenroth Robert-Koch-Straße 40 37073 Goettingen Germany

	Email: christof.lenz@med.uni-goettingen.de Tel: +49 551 39 12501