# Cooperation Agreement

between
DECRETO DEL DIRETTORE GENERALE - N. 4661 del 18/11/2026 - Allegato Utente 1 (A01)

Charité – Berlin University of Medicine
represented by the Chairman of the Executive Board,
the Chairman being represented by the Commercial Director of the Faculty,
Charitéplatz 1, 10117 Berlin, Germany

Implementing clinic/institute body:
Deutsches Herzzentrum der Charité

Person responsible for project management:
Prof. Dr. med. Christian Stoppe

- hereinafter referred to as "**Charité**" -

and

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico
represented by the Chief Scientific Officer, Prof. Fabio Blandini duly authorized by virtue of Council Resolution n. 10 of 27.03.24, via Francesco Sforza 28-20122 Milano

Person responsible for project management:
Prof. Vittorio Scaravilli

- hereinafter referred to as "Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico" -

- hereinafter all individually and collectively referred to as the "**Contractual Partners**" -

## Preamble

The Contractual Partners intend to jointly implement the project entitled

"Antioxidant Treatment with Vitamin C in Cardiac Surgery Patients – A Pilot Randomized Controlled Trial (The ACCURATE Study)"

(hereinafter referred to simply as the "**Project**").

The ACCURATE study, sponsored by the Charité – Berlin University of Medicine, was a randomized, open label, controlled clinical pilot trial which aimed to evaluate the effect of vitamin C on high risk patients undergoing open-heart surgery with the use of cardiopulmonary bypass (CPB). The primary objective was to assess efficacy of vitamin C with standard of care compared to standard of care only in reducing IL-6 as a marker of inflammation from before cardiac surgery until 96 hours after surgery. Within this study blood samples were collected until 72 hours after surgery from all patients.

The Contractual Partners therefore conclude the following Cooperation Agreement:

## § 1 Subject of cooperation

(1) The subject of the Agreement is cooperation with respect to in the measurement of inflammatory biomarkers using the Randox MultiSTAT on samples collected within the ACCURATE study.

(2) The respective contributions of the individual Contractual Partners and the schedule can be found in the project description (Annex 1).

(3) The project work is to be carried out in accordance with the relevant laws, guidelines and other regulations, where applicable. Any necessary registrations and/or permits are to be obtained in good time.

(4) The Contractual Partners shall each appoint a project manager. The project managers shall be responsible for the proper execution of the work.

Charité hereby appoints the following as project manager: Prof. Dr. med. Christian Stoppe

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico hereby appoints the following as project manager: Prof. Vittorio Scaravilli

Should a project manager resign during the term of the Agreement or for any other reason relinquish the project management, a staff member equally qualified to carry out the research work can be appointed as successor after informing the other Contractual Partner. If this is not possible or if the other Contractual Partner does not agree with the appointed successor for a justified reason, the Contractual Partners shall mutually agree to terminate the Agreement. Should this also not be possible, the Agreement may be terminated prematurely for cause.

(5) The Contractual Partners shall undertake to fulfil the coordinated areas of responsibility and subtasks. The Partners shall discuss among themselves the task descriptions, schedules and all information necessary for the execution of the Project.

(6) Each Partner shall be responsible for the performance of the tasks it has taken on.

## § 2 Funding

The Material is supplied without cost. Each Contractual Partner shall bear its own costs incurred in connection with the implementation of this Agreement. However, Charité agrees to pay any transfer, shipping or other reasonable fees due in connection with the transfer of the Material under this Agreement.

## § 3 Existing intellectual property

(1) Each Contractual Partner is and shall remain the owner of its intellectual property (protected and unprotected) existing at the time of conclusion of this Agreement.

(2) Each Contractual Partner shall grant the other Contractual Partner a free, non-exclusive, non-transferable and non-sublicensable right of use for this pre-existing intellectual property for the

duration of the Project, in so far as this is necessary for the performance of this Agreement and provided there are no conflicting third party rights. In particular, a right of use granted hereunder shall not give rise to any entitlement to process or modify the invention and the intellectual property right.

(3) In so far as the pre-existing intellectual property of a Partner is required for the exploitation of the work results or for use for purposes outside of or after the end of the Project, the respective other Partner may be granted a non-exclusive right of use thereto – provided there are no conflicting third party rights – at standard market conditions. Further details shall be mutually agreed between the Contractual Partners in a contract entered into separately from this Agreement.

(4) In the case of patentable and non-patentable work results, standard market conditions are understood to mean the licensing rates that are typical for the industry, taking into account the respective inventor's share.

(5) If conflicting third party rights become known in accordance with § 3(2) and § 3(3), the Contractual Partners shall inform one another of this immediately to the best of their knowledge and belief. The Contractual Partners shall not be obliged to conduct searches for property rights or, in general, to conduct searches for conflicting third party rights that go beyond what is usually practised by the Contractual Partner.

(6) Each Contractual Partner acknowledges that acts of use within the scope of the Project that concern the information and objects obtained from the other Contractual Partner shall not give rise to a right of prior use.

## § 4 Rights to the work results

(1) The Contractual Partner from whom the work results (patentable and non-patentable) developed within the scope of the Project originated shall be entitled to these results. Jointly developed work results belong jointly to the Contractual Partners in proportion to the shares to be allocated to each Contractual Partner.

(2) Work results are all results, including reports and documents prepared, that are obtained by the Contractual Partners in the course of carrying out their work within the scope of the Project (e.g. expertise, inventions, works protected by copyright, software).

## § 5 Rights of use of non-patentable work results

(1) Each Contractual Partner shall receive a free, non-exclusive, non-transferable and non-sublicensable right of use for the non-patentable work results to which the other Contractual Partner is entitled for the duration and purposes of the Project. In so far as the non-patentable work results of a Partner are required for commercial exploitation or for purposes outside of the Project or after the end of the Project, another Partner may receive a non-exclusive right of use for this at standard market conditions. Further details shall be mutually agreed between the Contractual Partners in a contract entered into separately from this Agreement.

(2) All Contractual Partners shall receive, free of charge, a non-exclusive, non-transferable right of use for non-commercial research and teaching activities for non-patentable work results, in so far as this is legally permissible.

## § 6 Patentable work results

(1) Should employee inventions arise during the implementation of the Project, the inventors must report this in writing to their employer. . The Contractual Partners shall inform one another of the disclosure of the invention in writing without delay.

(2) In the case of joint inventions, the Contractual Partners involved shall immediately agree on the further course of action, in particular the protection under property law, and shall record the results in a written report. In the case of joint inventions, industrial property rights will be applied for in the name of the Contractual Partners involved; for this purpose, each Contractual Partner shall make unlimited use of the inventor's share of its employees notified to it in accordance with applicable laws.

(3) In the case of joint inventions, each of the Contractual Partners involved may only dispose of the invention or joint property right with the prior written consent of the other Contractual Partner (e.g. licence, sale). Such consent may not be unreasonably withheld.

(4) If a Contractual Partner waives the application and/or maintenance of an industrial property right or industrial property right share, it shall first offer this to the other Contractual Partner for takeover. That Contractual Partner shall declare no later than eight (8) weeks after receipt of the takeover offer whether it will accept the offer. All costs arising from the takeover, including inventor's remuneration, shall be borne solely by the party taking over.

(5) Freelance inventors involved in the Project (e.g. students, doctoral candidates) must be obligated in writing to report and transfer their rights to any inventions prior to the start of their participation in the Project.

## § 7 Rights of use of patentable work results and exploitation

(1) The Contractual Partners are interested in the commercial exploitation of the results of their work and will carefully examine the exploitation possibilities for patentable and non-patentable results. Each Contractual Partner shall have the right to entrust a collecting society instead of itself with the handling of the application and the exploitation and therefore to disclose the necessary information to such society, if required.

(2) Work results that belong to one Partner alone shall be exploited by that Partner alone. The details of the exploitation of joint results shall be determined in a separate exploitation agreement between the Contractual Partners once the results are available.

(3) In the case of an invention, the Contractual Partners undertake to conduct negotiations constructively and in a timely manner. The Contractual Partners declare that they will carry out the necessary steps to safeguard the interests of both parties, in particular the decision on a patent application, in such a way that the (short) deadlines of the German Employee Invention Act can be met. The Contractual Partners are aware that, pursuant to Section 42 of the German Employee Invention Act, the university inventor is usually entitled to disclose the employee invention two months after the notification of their intention to disclose.

(4) All Contractual Partners shall receive, free of charge, a non-exclusive, non-transferable right of use for non-commercial research and teaching activities for patentable work results, in so far as this is legally permissible.

## § 8 Publications

(1) Work results that are attributable to one Contractual Partner alone may be published by the latter. Such publications shall be submitted to the other Partner in due time before their first publication for information purposes.

(2) Work results that are attributable to several Contractual Partners may only be published by those Contractual Partners following consultation and in mutual agreement. For this purpose, the Contractual Partners shall submit the manuscripts of planned publications and presentations to the other Contractual Partner for review at least thirty (30) days prior to the planned publication in order to give the other Contractual Partner the opportunity to comment. Proposed amendments will be taken into account, provided that they do not negatively impact upon the scientific character or neutrality of the publication. In exceptional circumstances, a postponement of the publication for a maximum of ninety (90) days after submission of the manuscript may be requested if and to the extent that this is strictly necessary to protect intellectual property. If, after thirty (30) calendar days from the date of delivery, no written and substantiated objection has been raised, the consent to publication shall be deemed to have been granted. Timely receipt by the recipient shall be required in order to meet the deadline. Publication shall always include a reference to the collaboration and the name of the Contractual Partner.

## § 9 Trademark protection

(1) The Contractual Partners shall mutually acknowledge one another's trademark rights and rights to the use of a name. Neither Contractual Partner shall use the other Contractual Partner's name or trademarks, in whatever form and for whatever purpose and regardless of the medium, without the other Contractual Partner's prior written consent.

(2) This does not include the naming of names within the scope of the usual naming of authors in scientific journals or official study registers (such as www.clinicaltrials.gov). For the avoidance of all doubt, it is clarified that, for example, mentioning the name on one's own homepage or in so-called popular science media does not constitute naming within the meaning of this paragraph.

## § 10 Confidentiality

(1) **Duty of confidentiality.** The Contractual Partners undertake to keep confidential all work results, trade secrets, expertise, technical descriptions and evaluations, inventions as well as other information and data requiring protection (hereinafter referred to as "Confidential Information") belonging to the other Contractual Partner and made available to one another or that they otherwise become aware of within the scope of this cooperation, to refrain from making them available to third parties either directly or indirectly and to use them exclusively for the purposes of the execution of the Agreement and the Project.

(2) **Scope of Confidential Information.** The above duty of confidentiality shall include all information that is designated as such verbally or in writing, or the confidentiality of which is readily apparent to the receiving Contractual Partner from the circumstances.

(3) **Effectiveness of the duty of confidentiality.** The foregoing obligation to maintain the confidentiality of Confidential Information shall extend beyond the term of this Agreement for five (5) years, regardless of whether the Agreement is terminated ordinarily or for cause.

(4) **Exceptions.** The following shall not be covered by the duty of confidentiality:

(a) information that was generally known at the time of signing of this Agreement or that becomes generally known at a later date without any breach of this Confidentiality Agreement having taken place,

(b) information that the recipient has already obtained knowledge of in a lawful manner prior to the conclusion of this Agreement,

(c) information that the recipient has received from a third party authorised to disclose the information,

(d) information that must be disclosed on the basis of a statutory, judicial or official order,

(e) information that has been developed by the receiving Contractual Partner independently of the information received on the basis of this Agreement, or

(f) information that the Contractual Partners agree in writing is not to be treated as confidential.

The burden of proof for the non-existence of Confidential Information as described in § 10(4) lies with the Contractual Partner who invokes this. In the event of a statutory, judicial or official order pursuant to § 10(4)(d), the recipient shall – to the extent permitted by law – notify the Contractual Partner that provided the information of this without undue delay, support the measures put in place by the latter to protect the Confidential Information to the reasonable extent permitted by law, and limit disclosure to that which is absolutely necessary to fulfil the obligation.

(5) **Technical/organisational confidentiality measures.** Each of the Contractual Partners shall ensure confidentiality by technical means and through other measures that are appropriate under the circumstances. This shall apply in particular to the storage and transmission of electronic data. The designation of information as confidential need not be made individually for each piece of information. Measures can be taken for certain categories of information, e.g., through general technical access barriers, through access and authorisation regulations, or through general internal guidelines and instructions, as well as through regulations in employment contracts.

(6) **Appropriateness of confidentiality measures.** Criteria for the appropriateness of confidentiality measures are, in particular and taking account of the specific circumstances of use, the nature and value of the trade secret and its development costs, the nature of the information, the significance for the owner, the size of the organisation, the customary secrecy measures in this organisation, the way in which the information is marked and any contractual arrangements agreed with employees and alliance partners for this purpose. Economic value is deemed to exist if obtaining, using or disclosing the information without the consent of the Contractual Partner is likely to damage the interests of the holder of the trade secret by undermining its scientific or technical potential, business or financial interests, strategic position or competitiveness. Accordingly, the measures are appropriate in particular if they are suitable for preventing unauthorised persons from accessing the information and expertise. The current state of the art and the economic reasonableness of the measures to be taken must be taken into account. Proof of this can be provided in particular by an IT compliance system, compliance with corresponding DIN or ISO standards or the corresponding BSI basic protection catalogue.

(7) **Extension to employees and third parties.** All persons working on the Project, including commissioned third parties, must be demonstrably included in the obligation to maintain secrecy. In the case of employees, the confidentiality obligation must be structured in such a way that the employee is bound to confidentiality to the extent permitted by law or collective bargaining agreements even after termination of the employment relationship. In the case of breaches of

the obligation to maintain confidentiality caused by persons working on the Project on behalf of a Contractual Partner, that Contractual Partner shall be liable as if it had caused that breach itself. The rights and obligations of employee representatives and whistleblowers pursuant to Section 5 of the German Trade Secrets Act (GeschGehG) shall remain unaffected. For public sector employees, the legal obligation to maintain confidentiality pursuant to Section 37 of the German Civil Servant Status Act (BeamtenstatusG) and Section 3(2) of the bargaining agreement for public employees of German states (TV-L) as well as Section 203(2) of the German Criminal Code (StGB) already applies within the meaning of Section 1(2) GeschGehG. Affiliated companies within the meaning of Section 15 et seq. of the German Stock Corporation Act (AktG) shall not be deemed third parties within the scope of this provision. The Contractual Partners shall ensure that the companies affiliated with them comply with the confidentiality obligations under this Agreement.

(8) **Reverse engineering.** A Contractual Partner who has received Confidential Information may not use that Confidential Information for purposes other than those of the Project, exploit it commercially itself in any way or imitate it, in particular by way of so-called "reverse engineering", or have it exploited or imitated by third parties. In particular, it is prohibited to apply for industrial property rights – such as trademarks, designs, patents or utility models – on such Confidential Information.

## § 11 (a) Data protection

The regulations concerning the processing of personal data within the scope of the Project are attached to this Agreement as Annex 2**Errore. L'origine riferimento non è stata trovata.**.

## (b) Biomaterial transfer

For any exchange of human materials between Charité ("SUPPLIER") and Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico ("RECIPIENT") under this Agreement, the material transfer provisions detailed in Annex 3 shall apply.

## § 12 Liability

(1) The Contractual Partners shall carry out the work carefully and in accordance with recognised scientific standards. The Contractual Partners are aware of the success risk associated with the research work. Due to the research character of the work, the Contractual Partners do not guarantee that a specific work result will be achieved or that the work result can be used or commercially exploited for a specific purpose or that it is free of third-party property rights. Where conflicting property rights become known, the Contractual Partner shall immediately inform the other Contractual Partner of this.

(2) **Charité** shall be responsible for obtaining the informed consent and the necessary authorizations for carrying out the Project and send the samples to Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico. Under no circumstances shall Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico be considered responsible for such violations.

(3) Mutual liability shall be limited to intent and gross negligence. The above limitation of liability shall not apply to injury to life, body or health, in the case of mandatory statutory liability, such as under product liability law, or in the case of a breach of material contractual obligations (so-called "cardinal obligations"). Cardinal obligations are those obligations that must be fulfilled for

the proper execution of the Agreement and on compliance with which the Contractual Partner regularly relies and may rely.

(4) Liability for consequential damages shall be excluded, except in the case of intent.

(5) In so far as liability is excluded or limited, this shall also apply to the Contractual Partner's employees, legal representatives, vicarious agents and assistants.

(6) If necessary, the Contractual Partners shall support one another in defending claims by third parties by providing the necessary declarations and/or documents. This applies in particular to patent law disputes.

## § 13 Limits of the cooperation

(1) The Contractual Partners confirm that the conclusion of the Agreement shall have no influence on either Contractual Partner's sales transactions, in particular procurement processes/pricing, and that there are no expectations in this regard.

(2) The Contractual Partners undertake not to provide any gift, payment or other form of advantage to any person directly or indirectly involved in the execution of the Agreement without legal grounds, which could be seen as an incentive or reward for the conclusion or execution of any part of the Agreement.

(3) The association governed by the Cooperation Agreement does not constitute an external private corporation. The latter cannot act in an externally binding manner vis-à-vis third parties.

(4) No Contractual Partner shall be entitled to represent individual Contractual Partners or all Contractual Partners together. The Contractual Partners shall not use the Project title or a comparable sign describing or indicating the association of the Contractual Partners in legal transactions in such a way as to create the impression that the said Contractual Partners jointly represent individual or all Contractual Partners.

(5) No Contractual Partner shall be entitled to assign or transfer obligations arising from this Agreement in whole or in part.

## § 14 Term of the Agreement

(1) This Cooperation Agreement shall enter into force upon the last signature and shall end on 31 December 2029.

(2) Termination for cause shall remain unaffected. Cause shall be deemed to exist in particular if the terminating Contractual Partner cannot reasonably be expected to continue the contractual relationship until the agreed termination or until the expiry of a notice period, taking into account all circumstances of the individual case and weighing the interests of both parties.

(3) Notice of termination must be in writing.

(4) Those provisions of this Agreement that the Contractual Partners wish to continue beyond the end of the Agreement, in particular § 3 - § 10, shall continue to apply in the event of termination.

## § 15 Applicable law and place of jurisdiction

The Parties agree to remain silent.

(1) .

## § 16 Final provisions

(1) The following documents form an integral part of this Cooperation Agreement. The contents are binding for all Contractual Partners:

**Annex 1:** Project description
**Annex 2:** Data protection
Annex 3: Material transfer provisions

(2) Any changes and additions to this Agreement must be made in writing. No subsidiary agreements have been made; should these be made, they must also be in writing. This requirement for the written form can also only be amended in writing.

(3) Should individual provisions of this Agreement be invalid, the validity of the remaining provisions shall not be affected. In place of the invalid provision, a provision shall apply that comes closest to what the Contractual Partners intended or would have intended if they had been aware of the invalidity of the provision. The same shall apply to any contractual loopholes.

**********

On behalf of Charité

Berlin, on

Town/city, date

Dr. Katharina Flemming, Head of Business Division Research Services

On behalf of DHZC

_____

Dr. Rolf Zettl, Commercial Director of the DHZC

Acknowledged:

Town/city, date

Prof. Dr. med. Christian Stoppe

Project manager

**On behalf of** Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico

Berlin, on

Town/city, date

Prof. FABIO BLANDINI Chief Scientific Officer

Acknowledged:

Town/city, date

Prof. Vittorio Scaravilli

Project manager

Annex 1

# Project description

Initial situation:

The Material consists of biosamples which were collected from study participants within the ACCURATE study. These biosamples will be transferred from Charité to Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, where measurements will be conducted. These measurements involve inflammatory biomarkers, which will be done using the Randox MultiSTAT. The purpose of this is to identify distinct immune biomarker profiles, which will subsequently be analysed along with trial data to identify the presence or absence of an association with patient outcomes.

Time frame of the Project:

The Material shall be sent from Charité to Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico within Q4 2026. Upon arrival at Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinicothe samples shall be analysed and the results shared between the Contractual Partners in 2027. Publications are anticipated thereafter.

Project Organization and Distribution of Roles

Each respective Contractual Partner's Project Manager shall manage the logistics of sample shipment, coordinate communication between the Contractual Partners and other involved parties, oversee the respective site staff or lab personnel involved in the project, monitor finances and timelines, and support the implementation of data protection and data security measures agreed between the Contractual Partners.

Each respective Contractual Partner's site staff and/or lab personnel shall prepare and dispatch or receive and register the material shipment, maintain an auditable chain of custody, conduct the intended analyses of the material in accordance with the project protocol and applicable SOPs, and ensure appropriate documentation of sampling, shipment and analysis procedures and results.

Implementation of the Project:

The Material shall be sent from Charité to Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinicowhere the biosamples are to undergo an inflammatory biomarker measurement using the Randox MultiSTAT. The intended biomarkers include interleukin-1 beta (IL-1ß), interleukin-2 (IL-2), interleukin-6 (IL-6), interleukin-15 (IL-15), interferon gamma (IFN-γ), tumour necrosis factor alpha (TNF-α), monocyte chemoattractant protein-1 (MCP-1), ferritin and d-dimer. The data from the measurement will be shared between the Contractual Partners.

Authorship of any publications of the results achieved through this Project will be decided in accordance with normal academic practice, unless otherwise agreed upon between the Contractual Partner's Project Managers.

Annex 2

# Agreement on joint control over the processing of personal data in accordance with Article 26 of the General Data Protection Regulation (GDPR)

between

**Charité – Berlin University of Medicine**
represented by the Chairman of the Executive Board,
the Chairman being represented by the Commercial Director of the Faculty,
Charitéplatz 1, 10117 Berlin, Germany

Implementing clinic/institute body:
Deutsches Herzzentrum der Charité

- Controller within the meaning of the GDPR, hereinafter referred to as "**Charité**"

and

Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico represented by the Chief Scientific Officer, Prof. Fabio Blandini, duly authorized by virtue of a Council Resolution n. 10 of 27.03.2024 with registered offices at Via Francesco Sforza 28-20122 Milano Italy
- Controller within the meaning of the GDPR, hereinafter referred to as "Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico" -

- hereinafter all individually and collectively referred to as the "**Contractual Partners**" -

## Preamble

The Contractual Partners intend to cooperate within the framework of the ACCURATE study, a randomized, open-label pilot trial assessing vitamin C in high-risk cardiac surgery patients on cardiopulmonary bypass, evaluating its effect on IL-6 versus standard care (hereinafter referred to as the "**Project**"). The cooperation in the context of the Project requires the processing of personal data in respect of which the Contractual Partners – at least in part – jointly determine the purposes and means of data processing and to that extent consider themselves joint controllers within the meaning of Article 26 GDPR. For this reason, the Contractual Partners enter into the present agreement on joint control over the processing of personal data in accordance with Article 26 of the General Data Protection Regulation (hereinafter the "**Agreement**"):

## I) General remarks

This Agreement governs the rights and obligations of the Contractual Partners in relation to the joint processing of personal data. This Agreement applies to all activities in the course of which employees of the Contractual Partners or processors engaged by them process personal data in the context of the Project. The Contractual Partners have jointly determined the means and purposes of the processing activities described in more detail in II).

The subject matter of this Agreement is the processing of personal data by the Contractual Partners for the purpose of implementing the Project. The Contractual Partners hereby determine the processing steps in which personal data are processed under their joint control (Article 26 GDPR).

For the avoidance of doubt, with respect to any processing that falls outside the scope of this Agreement, each of the Contractual Partners shall remain solely responsible and fully liable as controller within the meaning of Article 4 GDPR and, to that extent, no responsibilities or obligations of any Contractual Partner towards the respective other Contractual Partner shall arise under this Agreement.

Unless otherwise specified in this Agreement, the terms used herein shall have the meaning ascribed to them in Article 4 GDPR.

## II) Data processing operations, legal bases and tasks of the Contractual Partners

A) The responsibilities and competences in the context of the implementation of the Project are set out in Annex A.

B) The subject matter of the processing, the type of data and categories of data subjects, and the purposes of the processing, are set out in Annex B and in the study protocol, to be annexed to the Main Agreement where available.

C) If necessary because of a data processing operation, the Contractual Partners shall adapt the provisions of this Agreement accordingly. In view of the obligations of the Contractual Partners as joint controllers, each of the Contractual Partners shall be responsible for informing the other Contractual Partner if it deems it necessary to adapt the Agreement.

## III) Principles relating to the processing

A) Each Contractual Partner shall ensure compliance with the statutory provisions, in particular the lawfulness of the data processing operations it carries out, including in the context of joint control. The Contractual Partners affirm and shall ensure that all personal data will be collected and further processed in accordance with the provisions of this Agreement and applicable data protection laws.

B) The Contractual Partners shall at all times ensure that they comply with the principles relating to the processing of personal data under Article 5 GDPR.

C) If one of the Contractual Partners is of the opinion that the other Contractual Partner has violated the provisions of the present Agreement or the applicable data protection laws within the scope of the execution of the former, it shall immediately notify the other Contractual Partner of this.

## IV) Expediency and data minimisation

A) The Contractual Partners shall store the personal data for which they are responsible in a structured, commonly used and machine-readable format, namelyas agreed in the Main Agreement Each Contractual Partner that collects data shall ensure that only those personal data are collected that are consistent with the specified, clear and legitimate purposes for the implementation of the Project and are strictly necessary.

None of the Contractual Partners shall make copies or duplicates of the personal data processed under this Agreement unless necessary for the implementation of the Project (including data backups) or for the purpose of complying with legal retention obligations.

## V) Location of the data processing

A) The Contractual Partners shall process personal data in the course of the implementation of the Project exclusively in the Member States of the European Union or in another state that is a party to the Agreement on the European Economic Area.

B) Paragraph A) shall apply accordingly to the use of processors in accordance with XIV).

## VI) Information to be provided to data subjects

A) The Contractual Partners undertake to provide data subjects with the information required under Articles 13 and 14 GDPR free of charge and in a concise, transparent, intelligible and easily accessible form, using clear and plain language. This information shall inform the data subjects about the allocation of responsibility for the processing of the personal data. In particular, information shall be provided on which Contractual Partner is responsible for the identifying data or the process of re-identification. This Contractual Partner should also be named as the contact person for safeguarding the rights of data subjects.

B) The Contractual Partners agree that the Contractual Partner collecting the personal data from the data subjects shall provide the information referred to in paragraphs 1 and 2.

## VII) Contact point for data subjects and reciprocal information requirement

A) The Contractual Partners shall take all necessary technical and organisational measures to ensure that the rights of the data subjects, in particular under Articles 12 to 22 GDPR, can be or are guaranteed at all times within the statutory time limits, in so far as these rights are not restricted by statutory provisions.

B) The Contractual Partner that is to process the identifying data in accordance with the Agreement shall be responsible for responding to requests from data subjects for the purpose of asserting their rights under Articles 15 to 22 GDPR. The Contractual Partners agree that in each case this Contractual Partner shall be named as the contact point for the data subjects. Data subjects may assert the rights to which they are entitled under Articles 15 to 22 GDPR against all Contractual Partners. Data subjects shall be informed of the contact point responsible for them and of their rights by the responsible Contractual Partner in accordance with VI).

C) The Contractual Partners will assist each other in responding to requests and giving effect to data subject rights. If a Contractual Partner receives a complaint, request or notice from a data subject whose data it did not collect, it will promptly notify the Contractual Partner that collected the data of the data subject's request. If a data subject contacts one of the Contractual Partners regarding the exercise of his or her data subject rights, in particular for information or the rectification or erasure of his or her personal data, the Contractual Partners undertake to forward this request without delay to the Contractual Partner whose sphere of activity is affected by the request, irrespective of the obligation to ensure the data subject right.

D) The Contractual Partners' responsible contact persons are:

| Position | Surname, first name | Email | Telephone |
|---|---|---|---|
| **Contractual Partner 1** | | | |
| [Project manager] | **Prof. Dr. Christian Stoppe** | **christian.stoppe@dhzc-charite.de** | **+49 177 30 99 896** |
| **Contractual Partner 2** | | | |
| [Project manager] | Prof. Vittorio Scaravilli | **vittorio.scaravilli@unimi.it** | |

The other Contractual Partner shall be notified without delay of any change to the respective contact person.

E) If a Contractual Partner uses a processor and the processor receives a complaint, request or notice from a data subject, the Contractual Partner that engaged the processor shall ensure that

the processor notifies the Contractual Partner that collected the data subject's data of the request.

## VIII) Erasure of personal data

A) If personal data are to be erased, the Contractual Partners shall inform one another in advance. The Contractual Partners may object to the erasure for a legitimate reason, for example if they have a legal obligation to retain the data or if the right to erasure is restricted by law.

B) Regardless of a request for erasure, the Contractual Partners shall erase the data when the project objective has been achieved and if there is no right to further retention.

C) Each Contractual Partner shall keep a record of the erasure of personal data, which is to be provided to the other Contractual Partner upon request.

D) Paragraphs 16 A) and C) shall apply accordingly in the event of requests for rectification or restriction of processing from data subjects.

## IX) Communication and notification obligations

The Contractual Partners shall inform one another without delay if they discover errors or irregularities with regard to data protection provisions when reviewing the processing activities within the scope of the Project.

## X) Procedure in the event of data protection incidents

A) The Contractual Partners are responsible for the notification and communication obligations resulting from Articles 33 and 34 GDPR vis-à-vis the supervisory authority and the data subjects affected by a personal data breach under their respective responsibility. Any required notification to the supervisory authority shall be the responsibility of the Contractual Partner under whose responsibility the personal data breach occurred. If the breach occurs under the responsibility of more than one Contractual Partner, the Contractual Partners shall consult with one another on how to proceed.

B) The Contractual Partners shall notify one another without delay, and in no circumstances more than 24 hours, after becoming aware of a possible personal data breach under their responsibility. If possible, this notification should already contain the information required under Article 33(3) GDPR.

C) Any required notification to the supervisory authority shall be the responsibility of the Contractual Partner under whose responsibility the personal data breach occurred *ALTERNATIVE: Contractual Partner 1 or 2*. If the breach occurs under the responsibility of more than one Contractual Partner, the Contractual Partners shall consult with one another on how to proceed. The Contractual Partners shall comply with the statutory time limit for notification within 72 hours. Any deviation from the time limit must be justified and documented.

D) If, due to a risk to the rights and freedoms of natural persons, data subjects are to be informed pursuant to Article 34 GDPR, the Contractual Partner that collected the personal data shall be responsible for this. The respective other Contractual Partner shall, to the best of its ability, support the responsible Contractual Partner, as per the previous sentence, in the fulfilment of its notification obligations and shall forward to the latter the information required to carry out the notification in each case without undue delay.

E) Where possible, the Contractual Partners shall coordinate with one another on any communication with the competent supervisory authority and/or the data subjects relating to a personal data breach before it is sent. The Contractual Partners shall promptly take all measures

within their areas of responsibility that are necessary to address or prevent data protection breaches and violations.

## XI) Data protection impact assessment (DPIA)

If a DPIA is required pursuant to Article 35 GDPR, the Contractual Partners shall assist one another and provide one another with the information necessary for its preparation. Projects for which a DPIA is to be carried out may only be started once the DPIA has been completed.

## XII) Documentation/accountability

Documentation within the meaning of Article 5(2) GDPR that serves to demonstrate proper data processing shall be prepared by each Contractual Partner in accordance with its legal powers and obligations and, if necessary, shall be retained beyond the end of this Agreement.

## XIII) Confidentiality, retention, state of the art, protection

A) The Contractual Partners shall ensure, within their area of responsibility, that all employees involved in data processing maintain the confidentiality of the data in accordance with Articles 28(3), 29 and 32 GDPR for the duration of their employment as well as after termination of the employment relationship and that these persons have committed themselves to confidentiality and been informed of the data protection provisions relevant to them prior to commencing their employment.

B) The Contractual Partners shall independently ensure that they comply with all statutory retention obligations existing in relation to the data. To this end, they shall take appropriate data security precautions (Article 32 et seq. GDPR). This applies in particular in the event of termination of the cooperation.

The implementation, pre-setting and operation of the systems shall be carried out in compliance with the requirements of the GDPR and other legislation, in particular in compliance with the principles of data protection by design and by default, as well as using appropriate technical and organisational measures in line with the state of the art.

## XIV) Contract processing

A) The Contractual Partners are entitled to use processors within the meaning of Article 28 GDPR for processing operations under their respective responsibility. The Contractual Partners shall each keep a list of processors engaged by them for processing operations under this Agreement. In the event of a legitimate interest (e.g. monitoring compliance with the obligations under this Agreement, request from a supervisory authority or a data subject), the Contractual Partners shall make the lists available to one another, unless the request can be answered by means of direct information provided by the respective Contractual Partner to the requesting person.

B) Processors already entrusted with processing operations at the time of conclusion of the Agreement and also used by the respective Contractual Partner to provide the processing operations under this Agreement shall be deemed to be approved by the other Contractual Partner.

C) The Contractual Partners shall inform one another in good time, and in any event at least one (1) month in advance, of any intended changes concerning the addition or replacement of subcontracted processors for the processing operations for which the Contractual Partners are joint controllers pursuant to II) and shall only use subcontractors that comply with the requirements of data protection law and the provisions of this Agreement. For the purposes of

this provision, subcontracted services do not include services that the Contractual Partners obtain from third parties as ancillary services in support of the performance of the Agreement, such as telecommunications services and maintenance. However, the Contractual Partners are obliged to enter into appropriate and legally compliant contractual agreements and to take control measures to ensure the protection and security of personal data, even in the case of externally contracted ancillary services. Each Contractual Partner shall have the right to object to the engagement of a specific processor for cause within fourteen (14) days of receipt of the notification of the intended engagement.

D) The Contractual Partners undertake to enter into a contract in accordance with Article 28 GDPR when using processors within the scope of this Agreement. The Contractual Partner engaging the processors must impose obligations on these processors regarding data protection, confidentiality and data security that meet the requirements of Articles 28 and 29 GDPR and are at least as stringent as those set out in this Agreement. If subcontracting is allowed, the Contractual Partners shall ensure that the processors impose corresponding obligations on these subcontractors.

## XV) Record of processing activities

Each Contractual Partner shall, in accordance with Article 30(1) GDPR, keep a record of the processing operations it carries out, including in particular a note on the nature of the processing operation under its joint or sole control.

## XVI) Audit rights

A) Each Contractual Partner shall have the right to audit the compliance of the other Contractual Partner with this Agreement if this is necessary in order to fulfil an obligation vis-à-vis a supervisory authority or to satisfy itself that the other Contractual Partner has adapted its operations to the provisions of this Agreement following a data protection incident.

B) If and to the extent that such an audit requires the performance of on-site inspections, such inspections shall ordinarily take place during normal business hours and without unnecessary disruption to operations. The Contractual Partner conducting an audit shall give reasonable advance notice to the other Contractual Partner of all circumstances related to the audit.

C) A Contractual Partner may engage a third party to carry out the audit. In such a case, the third party must be bound in writing to maintain secrecy and confidentiality, unless the third party is subject to a professional duty of confidentiality.

## XVII) Liability

A) Without prejudice to the provisions of this Agreement, in the event of unlawful data processing, the Contractual Partners shall, in accordance with Article 82(4) in conjunction with the first sentence of Article 82(2) GDPR, in relation to third parties, be jointly liable vis-à-vis the data subjects for any damage caused by processing that infringes the GDPR, unless any of the Contractual Partners can prove that it is not in any way responsible for the event giving rise to the damage (Article 82(3) GDPR).

B) In their internal relationship, the Contractual Partners shall, without prejudice to the provisions of this Agreement, only be liable for damage that has occurred within their respective area of responsibility.

C) If, pursuant to Article 82(4) GDPR, a Contractual Partner has paid the entire compensation to a data subject for the damage suffered, that Contractual Partner shall be entitled to recover from

the other Contractual Partner the part of the compensation that corresponds to that other Contractual Partner's share in the responsibility for the damage.

D) Paragraph C) shall apply accordingly in the event that a supervisory authority has imposed a fine on a Contractual Partner if and to the extent that the breach giving rise to the fine is based, in whole or in part, on a breach of this Agreement or the applicable data protection laws by one or more other Contractual Partner(s). Without prejudice to the foregoing, a Contractual Partner may seek indemnification for a fine only if it has made all reasonable efforts to defend against or reduce that fine in the context of administrative proceedings.

## XVIII) Miscellaneous

A) This Agreement shall remain in force, irrespective of the duration of the Project, until all data processed jointly by the Contractual Partners and/or any processors engaged have been erased, at which time it shall automatically cease to be in force.

B) In all other respects, the final provisions of the Main Agreement shall apply accordingly.

Annex A

Responsibilities and competences of the Contractual Partners

Editing note: Please mark with [X] to indicate who is responsible for which tasks and with [Y] to indicate merely a support function.

| Tasks according to GDPR | Contractual Partner 1 | Contractual Partner 2 |
|---|---|---|
| Determination of the purpose and means of data processing | X | Y |
| Determination of the type of personal data | X | Y |
| Article 26(2): Informing the data subjects about the essence of this Agreement[1] | X | |
| Article 13: Information to be provided where personal data are collected from the data subject[1] | X | Y |
| Article 14: Information to be provided where personal data have not been collected from the data subject | X | Y |
| Articles 15-18, 20: Data subject's rights of access, rectification and erasure/restriction of processing and data portability[1] | X | Y |
| Article 19: Notification obligation regarding rectification or erasure of personal data or restriction of processing[2] | X | Y |
| Article 21: Right to object, if applicable (not in case of consent) | X | |
| Articles 24, 32, 35, 36: Determination/documentation of technical and organisational measures, risk assessment, data protection impact assessment, where applicable, and consultation with the supervisory authority | X | |
| Article 28: Engaging processors | X | |
| Article 30: Maintaining the record of processing activities | X | |
| Article 33: Notification of personal data breaches[12] | X | Y |
| Article 34: Communication of a personal data breach to the data subject[12] | X | |

[1] Communication with the data subjects shall be carried out exclusively by the body that may lawfully access identifying data, see § 7 to § 10 of the Agreement.

[2] Communication between the Contractual Partners shall take place, where appropriate, in pseudonymised form, see § 7 to § 10 of the Agreement.

Annex B

Description of the processing activity and categories of personal data

| | |
|---|---|
| NATURE AND PURPOSE OF PROCESSING | ☒ Implementation of a research project as part of a specific project<br>☐ Processing for the purpose of future research<br>☐ Co-treatment or quality assurance |
| CATEGORIES OF PERSONAL DATA | ☒ Identifying data<br>these will be passed on to: Contractual Partners<br>☐ Account data<br>☒ Data relating to health, sexuality, ethnicity, religion or belief<br>Specifically:<br>☐ Imaging<br>☐ Photos/videos/gaits<br>☐ Voice/audio<br>☐ Genetic data<br>☐ Biomaterial samples |
| CATEGORIES OF DATA SUBJECTS | ☒ Patients/study participants<br>☐ Relatives of patients/study participants<br>☐ Employees<br>☐ Others (e.g. employees of contract processors) |
| DESCRIPTION of systems used for data processing | ☒ Paper form<br>☒ Internal electronic database<br>☐ External electronic database<br>☒ Internal electronic data processing systems<br>☐ External electronic data processing systems (e.g. APP on terminal devices, survey tools, algorithms, software)<br>☒ Laboratory |
| Recipient of personal data | ☒ Sponsor/research institution located in a country covered by the GDPR or with an adequate level of data protection<br>☐ Sponsor/research institution located in a third country without an adequate level of data protection |

## Annex 3: Material transfer provisions

SUPPLIER shall be Charité providing MATERIAL and Data to Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico (the "RECIPIENT")

### §1 Background

1. The SUPPLIER is in the possession of organ samples, human tissue and/or human biological material and information pertaining to the material as described in Appendix 1 (the "MATERIAL"). The MATERIAL is described in **Appendix 1.**

2. The RECIPIENT wishes to receive the MATERIAL for the purpose described in Appendix 1 (the "PURPOSE") according to the research plan for the Cooperation Agreement (the "CA") under the terms and conditions provided herein. The obligations of RECIPIENT herein described will apply to any biological material that incorporates the MATERIAL or any recombinant version thereof.

3. The SUPPLIER is willing to provide the RECIPIENT with the MATERIAL for the PURPOSE.

4. The MATERIAL requested by RECIPIENT has been collected and stored within the context of another research project as described in **Appendix 1.**

### § 2 Definitions

The meaning of defined terms shall apply throughout this Agreement.

"**GDPR**" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the Processing of Personal Data and on the free movement of such data, and repealing Directive 95/46/EC.

"**MATERIAL**" means ORIGINAL MATERIAL together with all fragments and mixtures thereof and together with PROGENY and UNMODIFIED DERIVATIVES; MATERIAL shall not include MODIFICATIONS or other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY or UNMODIFIED DERIVATIVES.

**"MODIFICATIONS"**: Substances created by the RECIPIENT which contain or incorporate the MATERIAL.

"**ORIGINAL MATERIAL"** is the material provided by the SUPPLIER as listed in **Appendix 1** is considered proprietary to the SUPPLIER.

**"PROGENY"**: Unmodified descendant from the MATERIAL (for instance, cell from cell, virus from virus, organism from organism).

"**PURPOSE**" means the intended use of the transferred MATERIAL in the context of the research project as described in **Annex1 and specified in Appendix 1**.

"**RECIPIENT SCIENTIST**" means a researcher that is employed by the RECIPIENT and is bound by confidentiality and non-use obligations in respect of the MATERIAL and who has signed the CA for acknowledgement.

**"UNMODIFIED DERIVATIVES"**: Substances created by RECIPIENT constituting an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL.

## § 3 The MATERIAL and the PURPOSE

1. RECIPIENT acknowledges that all rights, titles and interests in and to all the MATERIAL provided under this MDTA shall remain the property of the SUPPLIER.
2. SUPPLIER will use economically reasonable efforts to provide RECIPIENT with the MATERIAL described in **Appendix 1**.
3. RECIPIENT will not use the MATERIAL in human subjects, in clinical trials, or for diagnostic purposes involving human subjects.
4. RECIPIENT will use the MATERIAL solely for the PURPOSE as described in **Annex 1 1** and for no other purpose. RECIPIENT shall not transfer the MATERIAL to any third party that is not listed in **Appendix 1**. Any use beyond this PURPOSE and/or for any commercial purpose, such as for production, is prohibited under this MDTA. In particular, no rights are provided to use the MATERIAL or any related patents for profit-making or commercial provision of a service to a third party in exchange for consideration.
5. RECIPIENT acknowledges that the MATERIAL is experimental and will comply with all laws and regulations applicable to its handling and use.
6. Recipient and the RECIPIENT'S SCIENTIST agree to not distribute or release the MATERIAL to individuals and entities not mentioned in in this MDTA, except for the laboratory personnel working under the Recipient Scientist´s direct supervision and bound by obligations not less strict than those set out herein. Recipient shall also ensure that no one will be allowed to take or send the MATERIAL to any other location than described in **Appendix 1**, unless written permission is obtained from SUPPLIER.
7. Provisions of § 3 of this MDTA related to MATERIAL also apply for Personal Data, if applicable.

## § 4 Data Protection

1. The PARTIES acknowledge and confirm their understanding that for the purposes of this MDTA the SUPPLIER and the RECIPIENT are joint controllers of Personal Data within the meaning of Article 26 GDPR, according to regulations provided in **Annex 2**.

2. The MATERIAL derived from human specimens may be carriers of Personal Data.

3. The MATERIAL, the type of Personal Data, categories of Data Subjects and the purposes of the Processing are set out in **Appendix 1**.

4. The SUPPLIER confirms that the SUPPLIER is entitled to supply the MATERIAL and Personal Data to the RECIPIENT for the intended PURPOSE and that the SUPPLIER has met all legal requirements that might apply to the further Processing – secondary use and/or transfer – of the Personal Data and MATERIAL under applicable Laws. The legal basis for Processing of Personal Data is provided in **Appendix 1**.

## Appendix 1 MATERIAL and PURPOSE of the research with MATERIAL

### Title of project (in less than 30 words)

Antioxidant Treatment with Vitamin C in Cardiac Surgery Patients – A Pilot Randomized Controlled Trial (The ACCURATE Study)

### MATERIAL Request

**Please describe the requested ORIGINAL MATERIAL (e.g., sample type, quantity and data, if applicable) and its planned use (the PURPOSE) (if applicable, details such as place of use/processing; specific storage/reuse; data processing, donor consent, transfer).**

*Material description as requested by RECIPIENT / delivered by SUPPLIER:*

*Biosamples (i. e. blood plasma) from 16 patients collected within the ACCURATE study.*

*Including study title of cohort study or clinical study as stated in ethical votum and patient consent; ethical votum number referring to patient consent*

Antioxidant Treatment with Vitamin C in Cardiac Surgery Patients – A Pilot Randomized Controlled Trial

Study number/acronym: The ACCURATE Study

EU CT number: 2023-510561-10

Ethical votum number: B_01704

*Method abstract for intended PURPOSE:*

The biosamples will be transferred from Charité to Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico using a carrier provider. Upon arrival at Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico the biosamples will be stored stored at -80 °C until the intended measurement. The biosamples are to undergo an inflammatory biomarker measurement at University of Milan using the Randox MultiSTAT. The intended biomarkers include interleukin-1 beta (IL-1ß), Interleukin-2 (IL-2), Interleukin-6 (IL-6), interleukin-15 (IL-15), interferon gamma (IFN-γ), tumour necrosis factor alpha (TNF-α), monocyte chemoattractant protein-1 (MCP-1), ferritin and d-dimer. The data from the measurement will be shared between the Contractual Partners and the remainder of the biosamples will be destroyed.

### Research Question – Information given by [RECIPIENT/SUPPLIER]

**Please provide a clear description of the project and its specific aims in no more than 750 words. This should include specific details according to the project and PURPOSE of the research with MATERIAL (what you plan to do with the MATERIAL and include key references).**

| |
|---|
| The purpose of this Project is to identify distinct immune biomarker profiles, which will subsequently be analysed along with trial data to identify the presence or absence of an association with patient outcomes. |

**Deletion date of the Personal Data (please justify the deletion date as specifically as possible): – Information given by [SUPPLIER]**

| |
|---|
| As specified in the Informed Consent Form of the ACCURATE study, the personal data of the study participants shall be stored for a period of 25 years after completion or premature termination of the main study. After this period, all personal data shall be deleted. |

**Personal Data associated with the MATERIAL: –**

| | |
|---|---|
| **Data Subjects** | *The Personal Data transferred concern the following categories of Data Subjects (e.g., patients, study participants, employees, students, external persons, relatives, …):*<br><br>☒ Donors (Patients/ Study participants)<br>☐ Employees/ Research Staff<br>☐ … [Please specify] |
| **Purpose of the transfer** | *The transfer is made for the following purpose(s):*<br>*Refer to "PURPOSE" as described above.* |
| **Categories of Personal Data according to 4 and 9 GDPR** | *The Personal Data transferred concern the following categories of data:*<br>☒ (e.g. sample ID, age group, gender, location data, online identifier, …)<br>☐ (eg. contact information and relevant professional experience of research staff)<br>☐ … |

| | |
|---|---|
| | *The Personal Data transferred concern the following categories of sensitive data (Article 9 GDPR):*<br><br>☒ Data concerning health,<br><br>☒ Genetic data<br><br>☐ Biometric data<br><br>☐ Data concerning sexuality, ethnicity, religion or belief<br><br>*Including [if applicable]*:<br><br>☐ Images (or image types explicitly listed below)<br><br>☐ Photos/videos/gait patterns (Biometric data)<br><br>☒ DNA/RNA (Genetic data, e.g., whole genome data, RNAseq)<br><br>☒ Biomaterial samples (or list specifically below, such as cell line, muscle biopsy specimens, blood, etc.)<br><br>☐ [e.g. *symptoms, diagnoses, outcomes, mortality information, treatments, x-ray, MRT*]<br><br>☐ …<br><br>☐ … |
| Processors and other recipients or entities that will receive or have access to the Personal Data (if applicable) | *Unless otherwise agreed below, RECIPIENT shall not transfer or disclose Personal Data to any other entity which is not party to this MDTA.* |
| Location of the RECIPIENT | ☐ … Recipient with an adequate level of data protection or located in a country covered by the GDPR<br><br>☒ … Recipient without an adequate level of data protection (USA) (***Appendix 2 applies***) |

<table>
<tr><td colspan="2">Additional useful information (other relevant information):<br>☒ Paper form<br>☒ Internal electronic database<br>☐ External electronic database<br>☒ Internal electronic data processing systems<br>☐ External electronic data processing systems (e.g. APP on terminal devices, survey tools, algorithms, software)<br>☒ Laboratory<br>☐ Others [please specify]:</td></tr>
<tr><td rowspan="2">Contact point for data protection enquiries/<br>Data Protection Officer</td><td>For Charité as ☒ SUPPLIER or as ☐ RECIPIENT:<br><br>Charité – Universitätsmedizin Berlin<br>Data Protection Officer<br>Charitéplatz 1<br>10117 Berlin<br>Tel.: +49 30 450 580 016<br>Email: datenschutzbeauftragte@charite.de</td></tr>
<tr><td>For Fondazione IRCCS Ca’ Granda Ospedale Maggiore Policlinico as ☐ SUPPLIER or as ☒ RECIPIENT:<br>Fondazione IRCCS Ca’ Granda Ospedale Maggiore Policlinico<br>Research data protection officer<br>Via Francesco Sforza 28-20122<br>Milano<br>Email: giuridico.ricerca@policlinico.mi.it<br><br>[...]</td></tr>
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