AZIENDA OSPEDALIERA UNIVERSITARIA MEYER IRCCS

Determina del Dirigente n. 420 del 06-11-2024

Proposta n. 1115 del 2024

Oggetto: STUDIO CLINICO PROFIT DENOMINATO “AN OBSERVATIONAL STUDY OF GENETIC CARDIOMYOPATHY, DANON DISEASE”, CODICE PROT. RP-NI-A501-0223 – APPROVAZIONE SCHEMA CONTRATTO PER SERVIZIO INFERMIERISTICO A DOMICILIO

Dirigente: FERRIGNO MARIANGELA

Struttura Dirigente: CONVENZIONI E AFFARI GENERALI

AZIENDA OSPEDALIERA UNIVERSITARIA MEYER I.R.C.C.S.
Istituto di Ricovero e Cura a Carattere Scientifico
Viale Pieraccini, 24 - 50139 FIRENZE
C.F. P.Iva 02175680483

DISPOSIZIONE DIRIGENZIALE

Oggetto	Studio clinico
Contenuto	STUDIO CLINICO PROFIT DENOMINATO "AN OBSERVATIONAL STUDY OF GENETIC CARDIOMYOPATHY, DANON DISEASE", CODICE PROT. RP-NI-A501-0223 – APPROVAZIONE SCHEMA CONTRATTO PER SERVIZIO INFERMIERISTICO A DOMICILIO

Struttura	CONVENZIONI E AFFARI GENERALI
Dirigente Proponente	MARIANGELA FERRIGNO
Responsabile del procedimento	ALESSIO FABBIANO
Immediatamente Esecutiva	SI

Conti Economici			
Spesa prevista	**Conto Economico**	**Codice Conto**	**Anno Bilancio**

Estremi relativi ai principali documenti contenuti nel fascicolo		
Allegato	**N° di pag.**	**Oggetto**
1	6	Schema contratto

"documento firmato digitalmente"

IL RESPONSABILE S.O.S.D. CONVENZIONI E AFFARI GENERALI
(Dr.ssa Mariangela Ferrigno)

Richiamati:

- il Decreto Legislativo n. 502 del 30.12.1992 e successive modifiche ed integrazioni, recante "*Riordino della disciplina in materia sanitaria, a norma dell'art.1 della legge 23 ottobre 1992, n. 421*";
- il Decreto Legge n. 75 del 22 .06.2023, così come modificato dalla Legge n. 112 del 10.08.2023, recante "*Disposizioni urgenti in materia di organizzazione delle pubbliche amministrazioni, di agricoltura, di sport, di lavoro e per l'organizzazione del Giubileo della Chiesa cattolica per l'anno 2025"* ed in particolare l'art. 8-bis, contenente "*Disposizioni in materia di dirigenza sanitaria, amministrativa, professionale e tecnica del Servizio sanitario nazionale*";
- la Legge Regionale Toscana n. 40 del 24.02.2005 e successive modifiche ed integrazioni, di "*Disciplina del Servizio Sanitario Regionale*";
- la Legge Regionale Toscana n. 12 del 16.03.2023 e successive modifiche ed integrazioni "*Disposizioni in materia di istituti di ricovero e cura a carattere scientifico pubblici. Modifiche alla l.r. 40/2005*" con la quale si è proceduto alla disciplina degli istituti di ricovero e cura a carattere scientifico di diritto pubblico ed in particolare l'art. 13 con il quale sono state dettate le "*Disposizioni transitorie per il passaggio da Azienda Ospedaliero Universitaria Meyer ad Azienda Ospedaliera Universitaria Meyer IRCCS…*";

Dato atto che**:**

- con deliberazione del Direttore Generale n. 443 del 23.09.2022 l'A.O.U. Meyer ha disposto la presa d'atto del Decreto del Ministero della Salute del 02.08.2022, pubblicato nella Gazzetta Ufficiale n. 200 del 27.08.2022, con cui l'Azienda Ospedaliero Universitaria Meyer è stata riconosciuta Istituto di Ricovero e Cura a Carattere Scientifico (I.R.C.C.S.), per la disciplina di pediatria;
- con deliberazione del Direttore Generale n. 286 del 09.05.2024 è stato adottato ai sensi dell'art. 50 novies comma 3 della L.R.T. 40/2005 e s.m.i., a seguito dei pareri favorevoli della Giunta Regionale e del Ministero della Salute, il Regolamento di organizzazione e funzionamento dell'A.O.U. Meyer I.R.C.C.S.;
- con deliberazione del Direttore Generale n. 296 del 10.05.2024 è stato approvato il nuovo assetto organizzativo dell'A.O.U. Meyer I.R.C.C.S. il cui organigramma ha decorrenza dal 01.07.2024;

Richiamata la deliberazione del Direttore Generale n. 551 del 02.10.2024 con la quale si è provveduto, a seguito delle azioni di sistematizzazione dell'organizzazione aziendale, alla declaratoria delle funzioni attribuite e/o delegate dal Direttore Generale ai singoli Dirigenti Responsabili delle Strutture Aziendali, anche ai fini dell'individuazione delle competenze nell'adozione degli atti amministrativi;

Dato atto che il Responsabile della S.O.S.D. Convenzioni e Affari Generali, Dr.ssa Mariangela Ferrigno, con riferimento alla presente procedura, attesta la regolarità amministrativa e la legittimità dell'atto;

Ricordato che con disposizione dirigenziale n. 291 del 01.08.2024 questa Azienda ha autorizzato la conduzione dello studio osservazionale profit denominato "An Observational Study of Genetic Cardiomyopathy, Danon Disease", codice prot. RP-NI-A501-0223, sotto la responsabilità del Prof. Iacopo Olivotto;

Atteso che il promotore dello studio su citato, Rocket Pharmaceuticals, Inc., in linea con il protocollo di studio, ha proposto che talune attività infermieristiche correlate allo studio medesimo siano eseguite presso

il domicilio dei pazienti partecipanti allo scopo di minimizzare il disagio degli stessi e che, per la disciplina delle condizioni operative di dette attività, si è reso necessario sottoscrivere un contratto con il fornitore del servizio infermieristico a domicilio, IQVIA RDS, Inc., individuato dallo sponsor;

Riscontrata l'accettazione del Dr. Iacopo Olivotto della necessità di eseguire alcune attività infermieristiche nell'ambito della conduzione dello studio presso il domicilio dei pazienti che vi partecipano;

Verificato che dalla conduzione dello studio non derivano oneri economici a carico dell'IRCCS Meyer;

Ritenuto, pertanto, di prendere atto della sottoscrizione del contratto con IQVIA RDS, Inc. per la fornitura del servizio infermieristico a domicilio secondo lo schema che, allegato N. 1 al presente atto, ne forma parte integrante e sostanziale

Considerato che il Responsabile del Procedimento, individuato ai sensi della Legge n. 241/1990 nella persona del Dr. Alessio Fabbiano sottoscrivendo l'atto attesta che lo stesso, a seguito dell'istruttoria effettuata, nella forma e nella sostanza è legittimo;

DISPONE

Per quanto esposto in narrativa che espressamente si richiama,

1. Di approvare lo schema del contratto per la fornitura del servizio infermieristico a domicilio, da stipulare con IQVIA RDS, Inc. che, allegato N. 1 al presente atto, ne forma parte integrante e sostanziale.

2. Di precisare che dal presente atto non derivano oneri economici a carico dell'AOU Meyer IRCCS.

3. Di trasmettere il presente atto al Collegio Sindacale ai sensi dell'art. 42, comma 2, della L.R.T. n. 40/2005 contemporaneamente all'inoltro all'albo di pubblicità degli atti di questa A.O.U. Meyer I.R.C.C.S.

IL RESPONSABILE S.O.S.D. CONVENZIONI E AFFARI GENERALI
(Dr.ssa Mariangela Ferrigno)

SITE AGREEMENT FOR CLINICAL STUDY SERVICES

BETWEEN

IQVIA RDS, INC. with registered office at 2400 Ellis Road, Durham, NC 27703, USA**,** and represented by Eric Neeley, with registered office at 2400 Ellis Road, Durham, NC 27703, USA ("**IQVIA**")

AND

Azienda Ospedaliera Universitaria Meyer IRCCS, with registered office at Viale Gaetano Pieraccini 24, 50139 Firenze, Italy, tax code/VAT number 02175680483, and represented by the the Contracts and General Affairs Department Manager Dr Mariangela Ferrigno, delegated to sign the present contract by General Manager with resolution n. 551 of 2 October 2024 and domiciled for the purposes of this agreement at the same Hospital offices ("**Site**")

hereinafter also referred to individually as the "**Party**" and jointly as the "**Parties**"

RECITALS

A. IQVIA, a CRO (Clinical Research Organization), has entered into an agreement with Rocket Pharmaceuticals, Inc. ("**Sponsor**"), to participate, as service provider, in a clinical trial entitled "*An Observational Study of Genetic Cardiomyopathy, Danon Disease*" ("**Study**") which includes the provision of mobile health visits and other services as applicable, for the subjects enrolled in the study, as described under Clause 2 herein ("**Services**");

B. The Sponsor has engaged IQVIA to manage, oversee, and monitor certain aspects of the Study, including the performance of the Services; and

C. The Site agrees, also following agreement by Principal Investigator Prof. Iacopo Olivotto ("**Principal Investigator**"), to contract with IQVIA to request the Services, to be performed pursuant to the Study protocol;

D. IQVIA as delegated by the Principal Investigator agrees to provide the Services and enters into this agreement with the Site ("**Agreement**").

In consideration of the covenants and conditions hereinafter set forth, it is agreed by and between the Parties as follows:

1. PURPOSE OF THIS AGREEMENT

1. The work to be performed by IQVIA, as delegated by the Principal Investigator, shall be research nurse and phlebotomy services pursuant to the Agreement between the Sponsor and IQVIA in relation to the Study as agreed with the Site and the Principal Investigator. It is the Principal Investigator's right to decline any assigned mobile medical professional and to request an

alternatively trained mobile medical professional if the level of training and qualification is considered not to be appropriate for performing delegated tasks.

2. DESCRIPTION OF THE SERVICES

2.1 The Site may make use of the Services if the Study subject (or subject's legal representative) consents to such Services. After the subject consents to the Services, the Services will be carried out in accordance with the Study protocol with appropriate delegation from the PI as required by ICH GCP and each entity's policies and procedures.

2.2 In accordance with the Study protocol, the Services specifically include:

- Phlebotomy
- Home visits scoped for this study are: Month 1, Month 2, Month 3, Month 9, Month 15, Month 21. The study assessments are inclusive of: Review of concomitant medications, review of procedures/hospitalizations, review of medical history and cardiac biomarkers lab sampling.
- Selection, qualification, and training of assigned IQVIA's mobile medical professionals for off-site services
- Verification of identity of each mobile medical professional, including:
    - Proof of right to work according to applicable labor laws
    - Ensure professional registration and qualification
    - Review of employment history via personal résumé and references
    - Good Clinical Practice (GCP) certification (not older than 2 years)
    - Occupational health and safety documentation

2.3 IQVIA will provide the Institution/Principal Investigator with evidence of specific and relevant trainings and qualifications, a copy of the mobile medical professional's résumé, and GCP certification, for review, approval and filing in the Investigator Site File. It remains the Principal Investigator's decision on what tasks he/she delegates to and on who should be added to the Delegation and Signature Log.

2.4 IQVIA assigned mobile medical professional will be available to meet involved trial personnel at the Institution via a virtual meeting if requested by the Principal Investigator. The Principal Investigator will then sign the Delegation Log, which outlines respective tasks and responsibilities. IQVIA shall in any case ensure that the Delegation Log has been completed and signed prior to the mobile medical professional completing any tasks associated with an off-site visit.

2.5 IQVIA ensures that assigned mobile medical professionals complete the training as required by Rocket Pharmaceuticals, Institution and IQVIA to perform their respective tasks. Mobile medical professionals are trained by IQVIA staff based on training material approved by the Sponsor on all study related procedures (including AE/SAE collection) and will illustrate evidence of competency in which to complete their respective tasks as defined by the Study protocol.

2.6 Assigned mobile medical professionals are trained in safety measures to minimize exposure to infections (e.g. COVID-19) and has up-to-date training to control cross-infections.

2.7 It is the Principal Investigator's right to decline any assigned mobile medical professional and to request an alternatively trained mobile medical professional if the level of training and qualification is considered not to be appropriate for performing delegated tasks.

2.8 Operating conditions and procedures for the performance of the Services are specified in detail in a specific document to be shared between IQVIA and the Principal Investigator. The Principal Investigator shall in any case maintain ultimate responsibility for all medical decisions regarding the conduct of the Study, keeping adequate supervision over the Services carried out by IQVIA.

3. COMPENSATION

The Site is not liable for payments to IQVIA for the Services. The Sponsor shall compensate IQVIA for the Services provided by IQVIA themself under the terms and conditions of their agreement.

4. DURATION

This Agreement shall enter into force on the date of signature by the last Party and shall remain in full force and effect until the end of the Services performed within the Study.

5. REPRESENTATION AND WARRANTIES

5.1 IQVIA represents and warrants that it will provide the Services in compliance with the applicable laws and GCP regulatory guidelines, and will provide the necessary equipment, knowledge, and personnel, either directly employed by IQVIA or freely subcontracted by IQVIA, for the correct and diligent performance of the Services.

5.2 Each Party has all necessary corporate power and authority to execute, deliver and perform this Agreement. This Agreement constitutes the legal, valid, and binding obligation of such Party, enforceable against it in accordance with its terms.

6. INSURANCE

6.1 IQVIA will maintain insurance for the duration of this Agreement for a reasonable amount to cover its obligations under this Agreement.

6.2 No insurance policy shall be provided by the Site for the Services and staff employed by IQVIA for the performance of the Services.

7. ETHICAL CONDUCT

7.1 IQVIA declares that it has adopted its own set of policies and standard operating procedures which are internal documents. All personnel employed by IQVIA or freely subcontracted by IQVIA will undergo training of the applicable policies, standard operating procedures, study-specific training, and with appropriate delegation from the Principal Investigator, as required by ICH GCP.

7.2 Each party will comply with their own regulations to enforce fairness and transparency, avoiding any behaviour or action that may constitute mismanagement with corruptive purposes and, more generally, that is in contrast with the principles, values, and rules of ethical conduct. In this context, the Parties also undertake to cooperate in good faith to facilitate the full and correct implementation of their mutual obligations.

8. CONFIDENTIALITY

8.1 The Parties undertake to consider all data and information, exchanged or obtained, directly or indirectly, during or in connection with the performance of this Agreement, as well as the information originated by the Agreement itself as strictly confidential, and not to reveal said

confidential information to third parties without the prior written consent of the other Party, except in accordance with the section below.

8.2 The Parties undertake to consider the protection of subject confidentiality and the Informed Consent Form will also reflect this point.

8.3 The Parties undertake and guarantee to not communicate, duplicate or use the confidential information other than for the purpose of performing this Agreement and, in particular, to not disclose such confidential information to any third party other than the CRO, the Sponsor, and the personnel, subcontractors, or external consultants directly involved in the performance of this Agreement and, also in this case, only and exclusively for the purpose of the performance of this Agreement or for obligations set forth by any applicable law, including transparency legislation applying on the Parties.

9. DATA PROTECTION

9.1 Parties shall comply with the General Data Protection Regulation ((EU) 2016/679 - GDPR) and all applicable laws and regulations relating to the processing of personal data and privacy, including where applicable the guidance and codes of practice issued by the competent authorities.

9.2 IQVIA personnel employed for the Services will comply with the abovementioned laws on the protection of personal data and will make sure that personal data is safeguarded during the performance of the Services in accordance with applicable laws.

9.2 IQVIA is the data processor for the Sponsor of the Study and personnel employed for the Study is the authorized persons by IQVIA.

10. TERMINATION

10.1 Without prejudice to any right or action of each Party under civil, administrative or criminal law, if one Party commits a material breach of this Agreement and fails to cure such breach within thirty days from receipt of a written notice from the non-breaching Party specifying such breach, the non-breaching Party may terminate this Agreement with an additional written notice immediately effective upon receipt.

10.2 The Parties have the right to terminate this Agreement for cause other than material breach as set out above by giving prior notice by means of a 30 day written notice to the other Party.

11. AMENDMENTS

11.1 No waiver, alteration, amendment, or modification of any of the provisions of this Agreement shall be binding unless made in writing with express reference to this Agreement and signed by a duly authorized representative of each Party.

12. NOTICES

12.1 Any notice required by this Agreement shall be in writing and delivered to the addresses specified below or to such other address as each party may from time to time designate to the other in writing. Delivery shall be deemed received as follows - if prior to 4:00 pm on a business day in the jurisdiction of the recipient and otherwise on the next business day by: (a) personal delivery, when

delivered personally; (b) courier, upon courier's verification of delivery; (c) electronic mail transmission successfully received by the recipient.

If to Site:	Azienda Ospedaliera Universitaria Meyer IRCCS Viale Gaetano Pieraccini 24 50139 Firenze, Italy alessio.fabbiano@meyer.it
If to IQVIA:	IQVIA RDS Inc. Attn: Kat Burns and Sehar Paya 2400 Ellis Road Durham, NC 27703
With a copy to:	IQVIA RDS Inc. Attn: IQVIA Legal Dept. 2400 Ellis Road Durham, NC 27703
With a copy to:	notices.officeofgeneralcounsel@iqvia.com

13. Fiscal obligations

Stamp duties due for this Agreement shall be paid by IQVIA.

14. Applicable law

This Agreement is governed by the laws of Italy. For any disputes that may arise in relation to the interpretation, application and execution of this Agreement, without prejudice to the Parties' commitment to make a prior attempt at out-of-court settlement, the Court of Italy (Florence) shall have exclusive jurisdiction.

THE PARTIES ACKNOWLEDGE AND AGREE THAT EACH CLAUSE AND OBLIGATION OF THIS AGREEMENT HAS BEEN DULY PREPARED, UNDERSTOOD, AND ACCEPTED BY EACH PARTY AS A RESULT OF FAIR AND MUTUAL NEGOTIATIONS.

*** *** ***

[*signatures follow*]

IQVIA

Authorised representative

_____

_____

Date: _____

Azienda Ospedaliera Universitaria Meyer IRCCS

Authorised representative

Contracts and General Affairs Dept. Manager

_____

Dr.ssa Mariangela Ferrigno

Date: _____

For acceptance and acknowledgement

The Principal Investigator

Dr Iacopo Olivotto

_____

Date: _____