Cooperation Agreement

on

the collbaroation in the joint project entiteled

"Montenegro COVID-19 Clinical Associates Initiative - MoCCA"

as a subproject of the joint cooperation

"COVID-19 Response and Recovery Alliance for Montenegro and the Western Balkans -

CORRAL"

Project Number: 1368-1968 (D81968)

between

 the Federal Republic of Germany, represented by the German Federal Ministry of Health, represented by the President of the Robert Koch Institute, Nordufer 20, 13353 Berlin, Germany,

- hereinafter referred to as "RKI" -

2. the Charité – Universitätsmedizin Berlin, represented by the Chairman of the board, represented by Commercial Director of the Faculty, Charitéplatz 1, 10117 Berlin, Germany; executing institution: Department of Anaesthesiology, with a focus on Surgical Intensive Care Medicine, Project Leader: Director of the Clinic, Univ. Prof. Dr. med. C. Spies, Augustenburger Platz 1, 13353 Berlin, Germany,

- hereinafter referred to as "Charité" -

and

3. the Clinical Centre of Montenegro, represented by the Director of the KCCG, Ljubljanska bb, 81000 Podgorica, Montenegro

- hereinafter referred to as "KCCG" -

hereinafter, jointly or individually, referred to as "Party" or "Parties".

Preamble

WHEREAS, the **Parties** are collaborating within the frame of the Collaboration Agreement effective as of the 31.10.2021 (Collaboration Agreement) concerning the project entitled "Montenegro COVID-19 Clinical Associates Initiative (**MoCCA**)" (hereinafter referred to as the "**Project**") as a subproject to the joint collaboration. "COVID-19 Response and Recovery Alliance for Montenegro and the Western Balkans" (hereinafter referred to as "**CORRAL**").

WHEREAS, **RKI** has received funding from the **BMG** for the implementation of the **Project** (Grant period: 01.11.2021 to 31.12.2022) – file number: ZMI1-2521GHP924. Despite the **Project** being closed, the need has arisen to alter Section 5 of the Collaboration Agreement in order to enable KCCG to use the equipment as originally intended by the **Parties**.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOW\$:

Section 1: Subject Matter of the Agreement

This Amendment Agreement regulates the the relationship among the **Parties** with respect to the **Project**, according to the provisions of Section 15.1 of the Cooperation Agreement.

Section 2: Amendments

2.1 Section 5.2 of the Collaboration Agreement shall be amended as follows:

In accordance with its contribution under Section 2.6 d), Section 6.1 and Section 6.2, RKI will acquire and transfer all necessary training material and portable medical devices for training (e.g. mobile ultrasound device, portable blood gas analysis devices, telemedical devices) to KCCG. The maximum value of material incurred by RKI will amount to

- a) 20,000 EURO in 2021,
- b) 40,000 EURO in 2022

and hence to an overall maximum value of 60,000 EURO within the scope of the **Project**. This includes:

1 unit – InTouch Lite 3, Factory Refurbished - Robot for telemedicine, value excl. VAT: 35,000.00 EUR

2 units – Vscan Extend Dual DICOM, Portable ultrasound device, value excl. VAT: 11,500.00 EUR

with the commercial value amounting to 46,500.00 EURO excluding VAT in total.

2.2 Section 5.4 of the Collaboration Agreement shall be amended as follows:

With the transfer of the materials to KCCG according to Section 5.2, the ownership of these materials is also transferred to KCCG, i.e. the material becomes the property of KCCG. As the transfer of material is a contribution within the cooperation between the Parties, it naturally comes without any compensation or encumbrance to KCCG. The handover of the material shall be made through the Public Procurement Service

KCI EUKA

Preamble

WHEREAS, **RKI** has already actively participated in research in Montenegro before the COVID-19-pandemic. Additionally, **RKI** has conducted an Montenegro during the pandemic. Based on the results of needs were identified in the main areas of immediate response to COVID-19, but also to future threats. The good relationship between **RKI** and its long-term cooperation partner **Charité** with the Government of Montenegro with its Institute of Public Health (IPH) and WHO Montenegro provides an excellent opportunity to address these needs first in Montenegro, with the possibility to subsequently expand the subprojects to other states in the Western Balkans, namely Albania, Bosnia and Herzegovina, Kosovo, North Macedonia and Serbia (hereinafter collectively with Montenegro referred to as "WB6"), with Montenegro acting as a hub. The WB6 have been heavily affected by the COVID-19 pandemic.

WHEREAS, Charité is one of Germany's most research-intensive medical institutions. Charité has been involved in numerous international collaborations. Specifically, the partnership between RKI and Charité has been in place for many years having jointly implemented projects on a wide range of topics. Charité is also a long-term cooperation partner of the Government of Montenegro with its IPH and WHO Montenegro

WHEREAS, KCCG is a reference institution of the tertiary level of health care for the whole of Montenegro and the secondary level for five South-Eastern Montenegrin municipalities. KCCG performs highly specialised diagnoses, treatments, consultations, specialist and sub-specialist examinations. The aim of this exchange between clinicians of KCCG and of Charité is a more unified and stringent approach to the treatment of COVID-19 patients at KCCG and throughout the whole country of Montenegro by forming a national network and transferring the knowledge.

WHEREAS, **RKI** is the German national public health institute, responsible for the detection, prevention and control of diseases, in particular infectious diseases. It is a Federal Institute within the portfolio of the German Federal Ministry of Health (Bundesministerium für Gesundheit, hereinafter referred to as "**BMG**"). **RKI**'s stated goal is to assume even greater responsibility for international and global health issues and to thereby make an important contribution to health protection not only in Germany, but also worldwide.

WHEREAS, the Parties intend to implement the joint collaboration "COVID-19 Response and Recovery Alliance for Montenegro and the Western Balkans" (hereinafter referred to as "CORRAL"). CORRAL aims to support current response activities by establishing capacities that will likewise increase resilience to future threats, in particular, by means of implementing the four subprojects:

- "Montenegro COVID-19 Clinical Associates Initiative (MoCCA)",
- "Western Balkan Laboratory Network (WALTON)",
- 3. "MONTENEGRO VIRTUAL Emergency Operation Center (MovE)" and
- 4. "Field Epidemiology Training Programme (FETP-WB)"

Moreover, **CORRAL** aims to establish a strong bilateral partnership with Montenegro as a future hub for the other WB6 countries. The Parties plan to sign a letter of intent regarding the overall collaboration **CORRAL** in good time.

WHEREAS, the first sub-project to be established, namely MoCCA (hereinafter referred to as the "Project"), is the main objective of this agreement and aims to support a unified approach to the treatment of patients with COVID-19 and other severe diseases in KCCG by establishing of an international network of health care experts, including KCCG, Charité and other partners in Germany. It reflects the outcomes of two consecutive visits to Montenegro, and in-depths discussions between colleagues from KCCG and experts from the Charité and RKI. The Project will address clinical experts in the field of COVID-19 treatment, as well as intensive care unit (ICU) experts in general. The participating clinicians of KCCG and Charité aim to

build a network (herein referred to as the "MoCCA Network"), enabling a mutual exchange of experience and knowledge between KCCG and Charité. Special focus will be given to the rational use of antibiotics, anticoagulants and anti-inflammatory drugs. Furthermore, the Project aims to support the local development of guidelines and teaching material, the establishment of local networks and the use of digital tools for monitoring.

WHEREAS, the **Project** shall be carried out in cooperation by the **Parties** in accordance with the Grant Application. The Grant Application is attached as *Annex I* to this Agreement. According to *Annex I*, the **Project** is composed of six Modules identified by a multidisciplinary expert collaboration between **RKI** the **Parties**:

Module 1: Kick-off workshop in Podgorica

- Module 2: Training of one cohort of selected clinicians from Montenegro at Charité clinics in Berlin (2021)
- Module 3: Training of two cohorts of selected clinicians from Montenegro at Charité clinics in Berlin (2022)
- Module 4: At least two webinars for clinicians in Montenegro (2021/2022)

Module 5: Evaluation of the Project

 Module 6: Workshop with participation from the WB6 to explore the way forward and additional approaches, such as telemedicine.

As regards the detailed conduction of each Module by the respective **Parties**, we refer to the Grant application in *Annex I* and the Budget Plan attached as *Annex II* to this agreement.

WHEREAS, **RKI**'s Centre for International Health Protection (**ZIG**) aims to contribute to the international effort against SARS-CoV-2 as part of its strategy to strengthen health sustainably in international contexts. The **Project** is *i.a.* intended to strengthen health systems through international collaboration. It shadowing in respiratory and positioning therapy and initiate exchange between intensive care specialists, infectiologists and critical care nurses from Montenegro and Germany in order to augment capacities in critical care medicine for COVID-19 as well as for long-term capacity building.

WHEREAS, **RKI** has received funding from the **BMG** for the implementation of the **Project** (Grant period: 01.11.2021 to 31.12.2021) – file number: ZMI1-2521GHP924 - (hereinafter referred to as "**Grant**").

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOW\$:

Section 1: Subject Matter of the Agreement

This Agreement is intended to specify the relationship among the **Parties** with respect to the **Project**, in particular concerning the respective responsibilities of the **Parties**, the management of the **Project** and the rights and obligations of the **Parties**.

Section 2: Contributions and Responsibilities of Parties

- 2.1 Each **Party** undertakes to take part in the efficient implementation of the **Project**, and to cooperate, perform and fulfil, promptly and on time, all its obligations under this Agreement including the Annexes thereto as may be reasonably required from it and in a manner of good faith.
- 2.2 Each **Party** undertakes to notify promptly any significant information, fact, problem or delay likely to affect the **Project**. The respective **Parties** will exchange and share among themselves the contents of the Grant allocation decisions, task descriptions, **Project** schedules as well as all data and information necessary to carry out the **Project**.
- 2.3 A Party that enters into a subcontract or otherwise involves third parties in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Agreement. Section 14.2 shall remain unaffected.

2.4 Charité will

- a) organise and conduct a kick-off workshop in Podgorica in 2021 jointly with all Parties,
- b) provide criteria for the common accountability framework jointly with KCCG,
- c) nominate suitable cohort candidates from KCCGs medical and nursing staff to participate in the training in Berlin jointly with KCCG, who will be chosen by the Steering Committee (see hereto Section 4.2),
- d) organise one training for a first cohort from **KCCG**s medical and nursing staff in 2021 and two more trainings in 2022 jointly with all **Parties**,
- e) conduct said training for the three cohorts from KCCGs medical and nursing staff at the Charité clinics in Berlin
- f) organise and conduct at least two webinar services of clinicians in Montenegro during the duration of the **Project**,
- g) hold a workshop with participation from all WB6 countries to explore and define next steps and additional approaches jointly with all **Parties**,
- h) prepare and conduct clinical case conferences jointly with KCCG,
- support the MoCCA Network in developing training materials and training guidelines,

- j) participate in the steering committee for the Project,
- k) conduct the evaluation exercises according to the accountability framework jointly with all **Parties**,
- I) contribute to the dissemination of results jointly with all Parties and
- m) assist, if required by **RKI**, in preparing manuscripts for progress or study reports for **BMG**, and participate in the preparation of other publications according to **Section 11**.

2.5 KCCG will

- a) organise and conduct a kick-off workshop in Podgorica in 2021 jointly with all Parties,
- b) provide criteria for the common accountability framework jointly with Charité,
- c) nominate suitable cohort candidates from KCCGs medical and nursing staff to participate in the training in Berlin jointly with Charité, who will be chosen by the Steering Committee (see hereto Section 4.2),
- d) organise one training for a first cohort from **KCCG**s medical and nursing staff in 2021 and two more trainings in 2022 jointly with all **Parties**,
- e) participate in the workshops, trainings, webinars and case conferences conducted by **Charité**,
- f) hold a workshop with participation from all WB6 countries to explore and define next steps and additional approaches jointly with all **Parties**,
- g) develop training materials and training guidelines within the MoCCA Network,
- h) participate in the steering committee for the Project,
- i) conduct the evaluation exercises according to the accountability framework jointly with all **Parties**,
- j) contribute to the dissemination of results jointly with all Parties and
- assist, if required by RKI, in preparing manuscripts for progress or study reports for BMG and participate in the preparation of other publications according to Section 11.

2.6 RKI will

- a) organise and conduct a kick-off workshop in Podgorica in 2021 jointly with all Parties,
- b) organise one training for a first cohort from **KCCG**s medical and nursing staff in 2021 and two more trainings in 2022 jointly with all **Parties**,

- c) conduct the evaluation exercises according to the accountability framework jointly with all **Parties**,
- d) procure and transfer training material (see hereto Section 5) to the corresponding sites as well as facilitate the traveling of the cohorts to the training sites in Berlin financially
- e) financially support the **Project** by the means of the **Grant** (see hereto **Section** 6) and in accordance with the Budget Plan (*Annex II*)
- f) jointly with all Parties contribute to the dissemination of results and
- g) prepare manuscripts a progress and a study report for BMG and participate in the preparation of other publications according to Section 11.
- 2.7 **Charité** and **KCCG** are obliged to submit a final scientific report about their respective results and contributions within the scope of the **Project** to **RKI**. The final scientific report must be submitted until the **30**th **of April 2022**.

Section 3: Implementation of research, transfer of personal data

- 3.1 Any research under this **Project** shall be carried out in accordance with the applicable laws and directives and/or regulations (for example genetic engineering, animal protection, radiation protection, etc.) good laboratory practices, guidance notes and procedures for each country. Where applicable, applications for the registrations, permits or ethical approvals required are to be made and collected in time
- 3.2 The **Parties** hereby agree that personal data will only be transferred and processed after the conclusion of appropriate additional contractual agreements and in accordance with all laws, regulations, good laboratory practices, guidance notes and procedures including, but not limited to, the Declaration of Helsinki applicable in Germany.

Section 4: Coordination, Steering Committee, project managers

- 4.1 Overall **Project** coordination is ensured by **RKI**. In particular, **RKI** has the task of coordinating the work of the individual **Parties** both in terms of technical implementation, e.g. travelling of the **KCCG** cohorts, and time. If deviations from the overall work schedule and timetable occur, it will draw the attention to the **Parties** as early as possible and propose measures to overcome the difficulties encountered. If deadlines cannot be met by one **Party**, the other **Parties** must be notified immediately.
- 4.2 Representatives of **KCCG** and **Charité** will form the Steering Committee. The Steering Committee is responsible for the content of teaching and other content related organisation of Webinars, Workshops and Trainings under this Project. **KCCG** and **Charité** shall arrange regular meetings of the Steering Committee to ensure proactive continuous exchange throughout the **Project**. The frequency of such meetings shall be mutually agreed by **KCCG** and **Charité**.

- 4.3 Throughout the **Project** communication process, all **Parties** shall provide a response to project emails exchanges in due time, if required. For emails with urgent requests and if required, all **Parties** shall provide a prompt response without undue delay.
- 4.4 Each **Party** appoints a project manager. The project managers are responsible for the proper execution of the work. The **Parties'** respective project managers' contact information are as follows:

Charité:

Project manager: Prof. Dr. Claudia Spies

Email: Claudia.spies@charite.de

Tel.: +49 (0)172 3940990

KCCG:

Project manager: Dr. Ljiljana Radulovic Email: ljiljana.radulovic@kccg.me

Tel.: +382 20 243 726 (office) / mob: +382 69 091 714 (mobile)

RKI:

Project manager: Dr Andreas Jansen and R. Sabrina Weiß

Email: JansenA@rki.de; WeissS@rki.de

Tel: +49 30 18754 3459

4.5 If, during the term of this Agreement, one **Party**'s project manager resigns or, for another reason, leaves the project management and the concerned **Party** has no other project manager who is already appointed, a similarly qualified employee shall be appointed as successor for the execution of the research work after notification to the other **Parties**.

Section 5: Travel expenses and Material

- 5.1 In accordance with its contribution under **Section 2.6 d**), **Section 6.1** and **Section 6.2**, **RKI** will acquire and transfer all necessary tickets for the travel of the **KCCG** training cohorts to Berlin in 2021 and 2022. The maximum value of tickets incurred by **RKI** will amount to
 - a) 15,000 EURO in 2021,
 - b) 35,000 EURO in 2022

and hence to an overall maximum value of 50,000 EURO within the scope of the Project.

- 5.2 In accordance with its contribution under Section 2.6 d), Section 6.1 and Section 6.2, RKI will acquire and transfer all necessary training material and portable medial devices for training (e.g. mobile ultrasound device, portable blood gas analysis devices, telemedical devices) to KCCG. The maximum value of material incurred by RKI will amount to
 - a) 20,000 EURO in 2021,
 - b) 40,000 EURO in 2022

and hence to an overall maximum value of 60,000 EURO within the scope of the Project.

- 5.3 **KCCG** will support **RKI** by identification of specific needs and facilitation of procurement and shipping, e.g. necessary customs clearance at country level.
- 5.4 With the transfer of the materials to **KCCG** according to **Section 5.1**, the ownership of these materials is also transferred to **KCCG**, respectively.
- 5.5 **KCCG** ensure to use the laboratory materials according to **Section 5** only for the purposes of this Agreement and in compliance with the applicable national and international laws.

Section 6: Financial regulations

- 6.1 **RKI** has been allocated a Grant by **BMG**. This funding is destined to cover the expenses incurred by the **Parties** during the **Project**. Hence, **RKI** will in accordance with the Budget Plan (*Annex II*) carry the costs of the **Project** for
 - a) travel of training cohorts to Berlin (see hereto Section 5),
 - b) material for the implementation of the **Project**, including training material and support tools in KCCG as well as (see hereto **Section 5**)
 - c) personnel in Germany for the implementation of the **Project** as well as the overall **Project** coordination.
- 6.2 As regards those costs, **RKI** will either make an upfront payment (see hereto **Section 6.8**), reimburse **Charité** for those costs under the following conditions:
 - The costs are actually incurred by said Parties during the term of the Agreement and must be necessary for the implementation of the Project,
 - b) they must be identifiable and verifiable, in particular recorded in the accounts of said **Parties** in accordance with the respective applicable accounting standards,
 - c) they must be reasonable and cost-efficient,
 - d) they must comply with the applicable national laws on taxes, labour and social security and
- 6.3 Personnel costs will only be covered in an upfront payment (see hereto Section 6.8) or reimbursed by RKI if the following conditions are met in addition to those stated in Section 6.2:
 - a) personnel costs have to be related to personnel employed by Charité for the implementation of the Project
 - b) personnel costs must be limited to salaries, social security contributions, taxes and other costs arising directly from national and international laws or the employment contract and
 - c) Charité declares that the costs are in accordance with its usual remuneration practices and are paid in a consistent manner whenever the same kind of work or experience is required regardless of the respective source of funding.

- 6.4 the maximum amount of the **BMG Grant** transferred to **Charité** will amount to
 - a) 15,810.00 EURO in 2021
 - b) 94,864.00 EURO in 2022

and hence to an overall maximum value of 110,674.00 EURO for the duration of the Project.

- 6.5 Reimbursement and/or direct payment to a product/service company requires
 - a) the submission of records and other supporting documents to prove the costs declared such as contracts, invoices and accounting records and
 - b) written confirmation by an authorised representative of the respective Party of the fact that the costs claimed meet the requirements laid out in Section 6.1.

All documents submitted to RKI must indicate the Project number: 1368-1968 (D81968)

- 6.6 All documents mentioned under Section 6.5 concerning costs incurred until the 10.12.2021 must be received by RKI by 10.12.2021 at the latest. Documents received subsequently will not be considered and the respective costs not be reimbursed. For the reimbursement of costs incurring in the period between the 11.12.2021 and the 31.12.2021, the respective Party has to submit a statement of anticipated expenditures showing the expected costs for this period by 10.12.2021. After the costs have actually incurred, the respective Party has to submit the respective confirmatory documents immediately, but no later than 15.01.2022. If these costs turn out to be higher than initially expected, there is no entitlement to additional payment. If the costs turn out to be lower, the repayment of the overpaid amounts must be reported to RKI by 15.01.2022 and initiated by 31.01.2022 at the latest. However, RKI asks Charité to provide all documents under this Section 6.5 as early as possible, preferably until the 30.11.2021.
- 6.7 All documents mentioned under Section 6.5 concerning costs incurred until the 15.10.2022 must be received by RKI by 31.10.2022 at the latest. Documents received subsequently will not be considered and the respective costs not be reimbursed. For the reimbursement of costs incurring in the period between the 16.10.2022 and the 31.12.2022, the respective Party has to submit a statement of anticipated expenditures showing the expected costs for this period by 15.10.2022. After the costs have actually incurred, the respective Party has to submit the respective confirmatory documents immediately, but no later than 15.01.2023. If these costs turn out to be higher than initially expected, there is no entitlement to additional payment. If the costs turn out to be lower, the repayment of the overpaid amounts must be reported to RKI by 15.01.2023 and initiated by 31.01.2023 at the latest.
- 6.8 As an exception to **Section 6.6** to **Section 6.7**, **RKI** may change the therein by unilateral declaration to **Charité** if necessary according to the requirements of the Grant allocation order by **BMG**. In addition, the **Parties** agree to further amend the Agreement by mutual agreement, if this is necessary according to the requirements of the allocation order by **BMG**.

- 6.9 Charité may request an advance payment up to a maximum of 80% of funds approved per calendar year in accordance with the Budget Plan (*Annex II*). The bank account details must be stated in each case.
- 6.10 The payments are made by transfer to a respective account to be designated by Charité in EURO.
- 6.11 **RKI** may refuse to make payments to a **Party** as long as that **Party** has failed to fulfil its obligations according to this Agreement.

Section 7: Right to audit and duty to inform

- 7.1 **RKI**, **BMG**, and/or the German Federal Court of Auditors (Bundesrechnungshof) may at any time perform an audit, or arrange for an auditor to perform an audit of the status and results of the implementation of **Project**, and the appropriate application of the **Grant** funding. The other **Parties** must keep the necessary documents ready for the audit, present these upon demand with reasonable advance notice from **RKI**, and remain available to provide further information as requested.
- 7.2 If it is shown, e.g., revealed by an audit according to **Section 7.1**, that a payment of **RKI** was not in accordance with the provisions of this Agreement, **RKI** shall be entitled to a refund from the respective **Party**. Further, if a **Party** has committed fraud or is in serious breach of its obligations under this Agreement or has made false declarations in connection with the reimbursement of costs, it is obligated to immediately repay the full amount of the funding received by **RKI** in connection with the implementation of the **Project** under this Agreement.
- 7.3 Each Party must promptly notify the other Party of all material changes of relevance to the Project, and must fulfil its duties to provide information.

Section 8: Pre-Existing Intellectual property

- 8.1 Each Party is and remains the owner of its intellectual property (protected and unprotected) existing as of the Effective Date of this Agreement as set out in Section 13.1 and intellectual property obtained by a Party outside the scope of this Project (hereinafter referred to as Pre-Existing Intellectual Property).
- 8.2 Each Party grants the other Party a free, non-exclusive, non-sublicensable and non-transferable right of use for the duration of the Project on its Pre-Existing Intellectual Property, insofar as this is necessary for the implementation of this Project and/or if needed for the non-commercial use of any Work Results (as defined in Section 9) provided that no third-party rights prevent this. Such right to use granted here does not, in particular, entitle to modify or change any inventions of the Parties that may result from the Project and does not affect Pre-Existing Intellectual Property rights contributed by any Party.
- 8.3 To the extent that **Pre-Existing Intellectual Property** of a **Party** is required for the commercial exploitation of any **Work Results** (as defined in **Section 9**) or for purposes outside the scope of or after the end of the collaborative **Project**, the **Party** may grant the other **Party** requiring such **Pre-Existing Intellectual Property**, a non-exclusive right of use to customary market conditions to the extent that no third-party rights conflict.

- 8.4 Insofar as conflicting rights of third parties become known, each **Party** shall inform the other **Party** immediately.
- 8.5 The Parties ensure that in accordance with **Section 2.3** regulations in **Sections 8.1 to**8.4 apply accordingly to **Pre-Existing Intellectual Property** contributed to the **Project** under the objectives of this Agreement by third parties.

Section 9: Work Results

- 9.1 **Work Results** are any outcome, including reports and documents prepared, obtained by the **Parties** in carrying out their tasks under the **Project** (e.g., know-how, data, inventions, results protected by copyright, software etc.).
- 9.2 Work Results (patentable and non-patentable) developed within the scope of the **Project** shall belong to the **Party** that has originated them. If the **Parties** have jointly originated them ("**Joint Owners**") and it is not possible to establish the respective contribution of each **Party** or to separate them for the purpose of applying for, obtaining or maintaining their protection, the **Joint Owners** must agree in writing on the allocation and terms of exercise of their joint ownership.

Section 10: Rights of use in relation to Work Results

- 10.1 Each **Party** shall be granted a free, non-exclusive, non-transferable and non-sublicensable right to use any **Work Results** created by both **Parties** and/or by the other **Party** for the duration and purpose of the **Project**.
- 10.2 In addition, after the termination of the **Project**, each **Party** shall be granted a free, non-exclusive, non-transferable, non-sublicensable and royalty-free right to use any **Work Results** created by the **Parties** and/or created by another **Party** for non-commercial purposes in scientific research, public service and training.
- 10.3 If any Work Results belonging to another Party are required for commercial exploitation or other purposes not covered under Section 10.1 and 10.2 by a Party, this Party may, upon request, obtain a non-exclusive right of use from the Party owning such Work Results under customary market conditions. Details shall be determined by the respective Parties in a separate agreement.
- 10.4 In accordance with the regulations of **BMG** on the allocation of the **Grant**, the **Parties** hereby grant **BMG** and its subordinate authorities a non-exclusive, non-transferable, royalty-free right of use to all types of use for the **Work Results** and developments of the **Project**. The right of use is unlimited in respect of place, time and content.

Section 11: Publications

11.1 **BMG** is entitled to publish a short report on the **Project** on the internet. This report will be produced by **RKI** with mandatory support of the other **Parties**.

- 11.2 The **Parties** are entitled to publish a short description of the **Project**, its scope of work and the distributions of contributions between collaborating parties as part of their regular public relations work with prior consent of **RKI**.
- 11.3 The **Parties** intend to publish the research results obtained within the **Project** jointly in a manuscript drafted by **RKI** with the support of the other **Parties**.
- 11.4 Other publications, not mentioned in **Sections 11.1** to 11.3, containing confidential information or **Work Results** of another **Party** or to which require the prior written consent of the other **Party**. No **Party** may unreasonably withhold its consent, if necessary subject to changes or deletions. If it does not object to a publication submitted to it (original text) within four weeks of receipt of the complete documents to be published, its consent shall be deemed to have been granted. The **Parties** agree that any publication shall be made in accordance with the protection of intellectual property rights, confidentiality obligations and the general principles of authorship like the "uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication" of the International Committee of Medical Journal Editors (http://www.icmje.org).
- 11.5 Each Party may publish its own Work Results in peer-reviewed journals with prior written approval of the publication by RKI.
- 11.6 In all publications or presentations, the **Parties** will point out that the **Project** has been a cooperation between **Charité**, **KCCG** and **RKI**. Further, in all publications or presentations, the **Parties** are required to expressly point out that financial support for the **Project** is provided by the Federal Republic of Germany. Therefore, any publication related to the **Project** must include the logos and texts available on the Internet at

https://styleguide.bundesregierung.de/sg-de/basiselemente/bildwortmarke/bildwortmarke-mit-foerderzusatz

using the following login details:

Username (Benutzername): cd_downloads_foerdermarke

Password (Passwort): CDM05bpa

In addition, all publications on the Internet should be barrier-free, e.g. using the format PDF/UA (https://www.access-for-all.ch/ch/barrierefreiheit/barrierefreie-pdf-dokumente/pdf-ua.html).

Section 12: Confidentiality

12.1 Each Party shall keep confidential all information, notices, documents and experiences of the other Parties which are known to it on the basis of this Agreement and which are identified as confidential or by the nature of which the receiving Party knew or should have reasonably considered it to be confidential ("Confidential Information"), for the duration of this Agreement and for 5 (five) years beyond the duration of this Agreement. Confidential Information of another Party/ other Parties shall be disclosed to third parties only with prior consent by the Party/ the Parties concerned and only to the extent necessary to fulfil this Agreement. Such third party shall be obliged, in writing, to maintain confidentiality of the Confidential Information in accordance with this Section 12. Each Party shall ensure that

the companies affiliated with it comply with the obligations of confidentiality under this Agreement and it shall be responsible for the unauthorized use or disclosure of **Confidential Information** by such affiliated companies.

- 12.2 The obligation of confidentiality shall not apply insofar as this **Confidential Information** demonstrably
 - a) was already known to the receiving Party prior to receipt of the Confidential Information:
 - b) was generally known before notification or became generally known on the basis of a notification without fault on the part of the receiving **Party**;
 - c) has been disclosed or made accessible by a third party with no obligation to maintain confidentiality; or
 - d) has to be compulsorily disclosed on the basis of law, regulations or official instructions provided that any involved Party is informed of this obligation in good time prior to disclosure and utilizes reasonable means of legal protection and procedural safeguarding of the confidentiality.

The Party who refers to one of the exemptions must provide the appropriate proof.

Section 13: Duration, termination

- 13.1 This Agreement enters into force retroactively as of 31.10.2021 and will end after BMG accepts the final report. The duration of the **Project** is from 01.11.2021 (Effective Date) until 31.12.2022. Any extension of the **Project** term by **BMG** shall automatically extend this Agreement if not agreed otherwise by the **Parties**.
- 13.2 Each Party's right to immediate termination for good cause remains unaffected.
- 13.3 In the event that a **Party** commits a breach or default of any of the terms or conditions of this Agreement, and fails to remedy such default or breach (if capable of remedy) within 14 (fourteen) days from the date of a written notice of such breach or default from **RKI**, **RKI** may in consultation with the other non-defaulting **Parties** decide to terminate the **Project** participation of the defaulting **Party** by written notice to the defaulting **Party**. A breach or default is deemed to exist, in particular, if a material term or condition of the Agreement, in particular but not limited to the obligations under **Section 2**, is breached.
- 13.4 The termination of this Agreement shall not affect the rights and obligations of any Party accrued as of the termination date of the Agreement. The provisions of **Sections 7 to 12** shall remain in force after the termination of this Agreement.

Section 14: Liability

14.1 The **Parties** shall carry out the work undertaken by them within the framework of the **Project** properly and to the best of their knowledge, considering the state of the art in science and technology. The **Parties** do not guarantee that the results of their **Work Results** are free of third party-rights and that specific results will be achieved. However, as soon as a **Party**

becomes aware of such third party-rights, it shall inform the other **Parties** thereof and take appropriate corrective action.

- 14.2 No Party shall be in violation of this Agreement for delays incurred due to force majeure and/or actions on the side of third parties if the Party can show that adequate steps according to Section 2.1 had been taken in a timely manner and the relevant information has been passed promptly according to Section 2.2 on to the other Parties.
- 14.3 Within the framework of the cooperation, the **Parties** will carry out the transmission of information with the care customary in their own affairs. The **Parties** shall not be liable for the correctness and completeness of the information provided by them within the framework of this Agreement or for any damage whatsoever resulting from the use of this information, either during the term of the cooperation or after the end of the contract.
- 14.4 Otherwise, the **Parties** their legal representatives and vicarious agents shall only be liable to each other for intent and gross negligence. In the event of gross negligence, liability shall be limited to the amount of the respective contribution.
- 14.5 The foregoing limitations or exclusions of liability shall not apply in the event of injury to life, limb or health.

Section 15: Form and contract hierarchy

- 15.1 Amendments and additions to this Agreement require the written agreement of all **Parties**. Signatures sent via email-fax shall also bind the **Parties** to this Agreement. This requirement can also only be amended in written form by the **Parties**.
- 15.2 Should the provisions of this Agreement contradict the provisions of *Annex I* in whole or in part, the provisions of this Agreement shall prevail. As an exception to this, the budget plan in *Annex II* shall prevail the budget specifications in *Annex I* and the specifications of this agreement if any contradictions arise.

Section 16: Applicable law and jurisdiction

- 16.1 This Agreement shall be governed by and construed under the laws of Germany excluding the conflict-of-law rules of private international law. For the sake of clarification, for all contractual relations that **Charité** or **KCCG** enters into with third parties for the implementation of this Agreement, e.g., but not limited to contracting of contractors, procurement of materials and equipment, this contractual provision does not apply.
- 16.2 In case of any dispute arising out or in relation to this Agreement the reprehensive bodies of the **Parties** will intervene to settle matters amicably. Lastly, the **Parties** can resort to the competent courts of Berlin (Germany) for settlements.

Section 17: Severability clause

Should individual provisions of this Agreement be invalid, the validity of the remaining provisions shall not be affected thereby. Instead of the ineffective provision, a regulation shall

be applicable that comes closest to what the **Parties** would have wanted or had wanted if the invalidity of the provision had been known to them. The same applies to any potential regulatory gaps in the agreement.

Section 18: No waiver

No waiver by a **Party** of any breach or default by any other **Party** shall operate as a waiver of any succeeding breach or other default or breach by such other **Party**. A **Party's** failure or delay in exercising any right or remedy provided under this Agreement or by law shall not constitute a waiver by that **Party** of that or other right power or remedy, nor shall it preclude or restrict such **Party** from any further exercise of that or other right or remedy.

Section 19: No assignment

Except as expressly provided in this Agreement, no **Party** may assign or transfer this Agreement as a whole, or any of its rights or obligations under it, without first obtaining the written consent of the other **Parties**; such consent may not to be unreasonably withheld or delayed.

Annexes:

- Annex I: Grant Application
- Annex II: Budget Plan

CORRAL-MoCCA-Cooperation Agreement, as on 08.12.2021

For KCCG

Place, date: Podgorica, 08.12.202

Rach louis

Dr Ljiljana Radulović,

Director of Clinical Centre of Montenegro

CORRAL-MoCCA-Cooperation Agreement, as on 08.12.2021

For Charité

Berlin, date:

Digital unterschrieben

Dr. Katharina von Dr. Katharina

Flemming

Flemming Datum: 2021.12.08 16:11:39 +01'00'

i.V.

Anne Großkopff

Commercial Director of the Faculty, Charité University Medicine Berlin (Kaufmännische Direktorin der Fakultät, Charité Universitätsmedizin Berlin)

For Charité: read and acknowledged

Berlin, date:

08.17 2.1

Univ. Prof. Dr. med. C. Spies

Director of the Clinic for Anesthesiology with a focus on Surgical Intensive Care Medicine, Charité University Medicine Berlin (Direktorin der Klinik für Anästhesiologie mit Schwerpunkt operative Intensivmedizin, Charité Universitätsmedizin Berlin)

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UNIVERSITÄTSMEDIZIN BERLIN Klinik für Anästhesiologie m.S. operative Intensivmedizin CCM / CVK
Direktorin: Univ.-Prof. Dr. med. Claudia Spies Campus Charité Mitte Charitéplatz 1 | D-10117 Berlin Telefon: +49(0)30 450 - 531 012 / 052 Telefax: +49(0)30 450 - 531 911 Campus Virchow-Klinikum Augustenburger Platz 1 | D- 13353 Berlin Telefon: +49(0)30 450 - 551 - 102/002/022 Telefax: +49(0)30 450 - 551 909

For RKI

Berlin, date: 03.42.2024

Prof. Dr Lothar H. Wieler

President of the Robert Koch Institute

Prof. Dr. Lars Schaade Vice President Robert Koch Institute Nordufer 20 D-13353 Berlin GERMANY

Crna Gora KLINIČKI CENTAR CRNE GORE Broj 03/01- 11970 Podgorica, N. 05. 20 Da

ROBERT KOCH INSTILLE



28 January 2011

Pobert Koch Institut zentrale@rki.de Tel: 149 (0)30 (3 1)4 (

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Robert Koch-Institut | Nordufer 20 | 13353 Berlin

Klinički Centar Crne Gore (KCCG) bjubljanska bb 81000 Podgorica Montenegro

Contact person: Dr. Ljiljana Radulović, Director KCCG lilliana.radulovic@kccg.rhe +382 20 243 726

Centre for International Health Protection ZIC1 - Information Centre for Internal area Health Protection

PROFORMA INVOICE

The listed device is sent on behalf of the Robert Koch Institute (German Federal Institute for Infectious and Non-communicable Diseases), Berlin, Germany, to the Clinical Centre of Montenegro (Klinički Centar Crne Gore) in Podgorica, Montenegro. The device will be used for information exchange between hospitals in the process of intensive care treatment of patients with in the actual outbreak situation of COVID-19. These items are non-infectious, non-toxic, nonexplosive, and not harmful to the environment or human health and are only used for medical treatment purposes.

All items are listed as follows:

| Product description | Unit price (EUR) | Quantity | Total price (EUR) | HS code |
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| InYouch Lite 3, Factory Refurbished / 20-20310 | 14,016.84 | 1 | 14,015.34 | 9517,18.0000 |

Manufactured by: InTouch Technologies Inc.

The total net value (for customs purpose only) is: 14,016.84 € The total gross weight is 174 kg.

The device concerned is not intended for sale and provided free of charge to of Monteneg-o, Podgorica. All materials are humanitarian goods

FOR CUSTOMS PURPOSES ONLY.

for olvan Of Andreas Jansen Head of the Unit 1G1 Ракочевић Сања

al Ministry of Hea

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Na osnovu Uredbe o Vladi Crne Gore ("Službeni list CG" br.80/08, 14/17 I 28/18) i Odluke o načinu ostvarivanja prava na oslobadjanje od plaćanja poreza na dodatu vrijednost i carine na medicinska sredstva i zaštitnu opremu koja se uvoze kao donacija, radi suzbijanja posljedica nastalih usljed epidemije zarazne bolesti COVID 19 ("Službeni list CG", br.32/20 i br.11/21), Ministarstvo zdravlja izdaje

POTVRDU

Da se donacija Robert Koch Institute iz Njemačke u 1 sistema za prenos informacija InTouch Lite 3 u okviru projekta u borbi protiv CoVid 19, koja je usmjerena na Klinički centar Crne Gore Crne Gore, u vrijednosti Eur 14.016,84, na osnovu odluke Ministarstva zdravlja vodi u evidenciji o medicinskim sredstvima i zaštitnoj opremi koja se uvoze u Crnu Goru, radi suzbijanja posljedica nastalih usljed pandemije zarazne bolesti COVID 19 i oslobađa se od plaćanja poreza na dodatu vrijednost i carine.

MINISTARKA

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Magyarország

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Email cim: schenker@DBSCHENKER.COM

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Vámeljárási megbízás visszaigazolás DEBER202085460

| Címzett: Klinicki Centar Crne Gore Dr. Ljiljana Radulovic Ljubljanska bb 81000 Podgorica Montenegro Kontakt: Dr. Ljiljana Radulovic | | | Funkció: Telefonsz: +36 1 27 Fax szám: | Novinszky | er.com |
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A fenti áruk megfelelő átvételének megerősítése.

Egyéb instrukciók:

contact consignee '+38269091714 Dr. Ljiljana Radulovic Kd-Nr. angefordert

Nemzetközi favarlevél (CMR)



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Letter of Intent

to

implement the joint cooperation project "COVID-19 Response and Recovery Alliance for Montenegro and the Western Balkans – CORRAL"

| petween |
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| 1. the Federal Republic of Germany, represented by the German Federal Ministry of Health, represented by the President of the Robert Koch Institute ("RKI"), Nordufer 20, 13353 Berlin, Germany, |
| and |
| the Charité – Universitätsmedizin Berlin, Department of Anesthesiology, represented by the Deputy Medical Director of the Charité, Augustenburger Platz 1, 13353 Berlin, Germany, |
| and The KCCC Liublianska |
| 3. the Clinical Centre of Montenegro ("KCCG"), represented by the Director of the KCCG, Ljubljanska |
| bb, 81000 Podgorica, Montenegro |
| and . |
| 4. the WHO Country Office Montenegro ("WHO Montenegro"), represented by the Head of WHO |
| Country Office, Serdara Jola Piletica br. 8, 81000 Podgorica, Montenegro |
| and ADU Džana |
| 5. the Institute of Public Health of Montenegro ("IPH"), represented by the Director of the IPH, Džona |
| Džeksona bb, 81000 Podgorica, Montenegro |
| |
| hereinafter, jointly or individually, referred to as "Partner" or "Partners". |

Preamble

Already before, the COVID-19-pandemic, RKI has been active in Montenegro. Additionally, it conducted an in-depth intra action review in Montenegro during the pandemic. Based on the results of the intra action review, several needs were identified in the main areas of immediate response to COVID-19, but also to future threats. The good relationship between RKI and its long-term cooperation partner Charité with the Government of Montenegro with its IPH and WHO Montenegro provides an excellent opportunity to address these needs first in Montenegro, with the possibility to subsequently expand the subprojects to other WB6, with Montenegro acting as a hub.

In the light of this, the Partners intend to implement the joint cooperation project "COVID-19 Response and Recovery Alliance for Montenegro and the Western Balkans" (hereinafter referred to as "CORRAL"). CORRAL aims to support current response activities by establishing capacities that will likewise increase resilience to future threats, in particular, by means of implementing the four subprojects

- "Western Balkan Laboratory Network (WALTON)",
- "Montenegro COVID-19 Clinical Associates Initiative (MoCCA)",
- "MONTENEGRO VIRTUAL Emergency Operation Center (MovE)" and
- "Field Epidemiology Training Programme (FETP-WB)"

The first sub-project to be established, namely, MOCCA, aims to support a unified approach to the treatment of patients with COVID-19 and other severe diseases in KCCG by establishing of a network of clinical companions. It reflects the outcomes of two consecutive visits to Montenegro, and in-depths discussions between colleagues from KCCG and experts from the Charité and RKI. MoCCA will address clinical experts in the field of COVID-19 treatment, and ICU experts in general enabling a mutual exchange of experience and knowledge between KCCG and Charité.

Declaration of Intent

The Partners agree that this Letter of Intent is neither intended to be legally binding nor to confer any legal rights or commitments nor to impose any financial or commercial responsibilities on any of the Partners. Such provisions and specifications are subject to separate cooperation agreements in writing to be duly signed by the legal representatives of the Partners.

Considering this, the Partners nonetheless express their serious intention to implement CORRAL in accordance with their commonly defined project goals.

For KCCG

Dr Ljiljana Radulović, Director of Clinical Centre of Montenegro For IPH

Dr Igor Galić Head of Institute of Public Health Montenegro

Signature

Podgorica, 24 September 2021

Signature:

Podgorica, 24 September 2021

For RKI

Dr Andreas Jansen, Deputy Head of Centre for International Health Protection, on behalf of President of the Robert Koch Institute, Prof. Dr Lothar H. Wieler

For Charité

Dr Joachim Seybold, Deputy Medical Director of

Charité - Universitätsmedizin Berlin

Signature:

Podgorica, 24 September 2021

Signature:

Podgorica, 24 September 2021

JZU KLINIČKI CENTAR CRNE GORE

Skladište: Glavni magacin KCCG:Prijemnice-OSSIT

ministarstvo zdravlja.

Prijemnica br. WH/IN/23/00155

Dobavljač:

Savezna Republika Njemačka koju prestavlja Njemačko

Datum:

23.03.2023

Status:

Gotovo

Narudžba: Otpremnica:

Faktura:

Ugovor o Saradnji (Donaciji) Projekat br.1368-1968 (D81968) od

08.12.2021

P15301

Broj Artikal Serija Rok Količina J.mj. Cijena Iznos [R-12043] Portabilni ultrazvučni aparat 5.750,0000 11.500,0000 kom. [R-12044] Robot za telemedicinu kom. 35.000,0000 35.000,0000 Ukupan iznos: 46.500,0000 €

Napomena:

Ažurirao:

Abdić Kenan

27.03.2023 10:37

Preuzeo:

Ovjerio:

Abdić Kenan

23.03.2023 10:23

23.03 2023 REVERS br. 72 Potvrđujem da sam primio iz ekonomata na upotrebu za Interna Klinika - Interivna jedinica sledeće Sunja Januaric Cijena NAIMENOVANJE 76635 Ol. 1Kgt. Robot Zu Telemedicina

29.03 2023 REVERS br. 17

Potvrđujem da sam primio iz ekonomata na upotrebu za
Ody, Centralne interivne Teranje Clena Bozović Cijena NAIMENOVANJE 76641 Ol. 1 Kor. Portabilni ultrazvek Telen Pagar Odobrava,