**DATA USE AGREEMENT**

This Data Use Agreement (hereinafter Agreement) is by and between

[name], having its principal office at [address], legally represented by ….. , hereinafter: ‘ abbreviation ’

And

**Maastricht University**, more specifically its Faculty of Health, Medicine and Life Sciences. School for Oncology and Developmental Biology (GROW)/ Department of Radiotherapie/ The D-Lab, having its principal office at Minderbroedersberg 4-6, 6211 LK Maastricht, represented by Prof. Dr. M. van Engeland, Scientific Director GROW, hereinafter referred to as UM or hereinafter: ‘UM’

and is effective as of the date of the last signature (the ‘Effective Date’)UM and Partner will individually be referred to as ‘party’ and collectively ‘parties’.

Party receiving the data will be referred to as ‘User’

Party providing the data will be referred to as ‘Holder’

**Whereas**

* the parties have provided and may provide each other with certain Dataset of a confidential nature concerning project/study which is enclosed as Annex 1;
* Holder is a research institute which manages the data obtained from the study [name study] with IRB registration number [number] that was collected and processed anonymously;
* Holder will remain owner of the data it provides to User and will keep all right, title and interest to the original data including all Intellectual Property Rights;
* Holder has made the data available as a service to the research community to be used for teaching and not-for-profit research purposes only;
* User has submitted a proposal requesting access to this data to examine [describe purpose];
* Holder is willing to grant User a non-exclusive license to use the data on the terms and conditions herein set forth;

**Now, therefore**, in consideration of the above premises, the Parties agree as follows:

**Article 1 Access to Data**

Holder shall provide User with access to certain data (‘Dataset’) in accordance with the terms and conditions of the Agreement. User will make a secure file using the secure dutch academic cloud “surfdrive” OR will transfer the data on hard drive.

**Article 2 Authorizes Parties**

The following individuals (‘Authorized Parties’) are authorized to use the Dataset or any part of it on behalf of the User and agree to abide by the terms and conditions of this Agreement:

Philippe Lambin, Prof. MD, PhD +32 475 259596, Philippe.lambin@maastrichtuniversity.nl

Registered employees from the Dpt of Precision Medicine, Maastricht University.

**Article 3 Permitted Use**

User, and any Authorized Party on User’s behalf, may use the Dataset only for the following purposes for [a period not to exceed ten (10) years from the Effective Date] or [for the time frame as indicated below], unless otherwise agreed upon in writing by the parties:

To perform the analysis as described in the proposal for analysis, which is enclosed as Annex 1]

During the time frame: 2020-2021

User agrees that this Dataset will not be used to treat or diagnose human subjects or for gain or commercial profit.

**Article 4 Conditions of Use**

User agrees and shall ensure that each Authorized Party agrees as follows:

1. Not to use or further disclose the Dataset or any information contained therein other than as permitted by this Agreement or required by applicable law;
2. To use the Dataset in compliance with all applicable statutes and regulations;
3. To remove or destroy the information that identifies the individual subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the permitted use;
4. To use appropriate safeguards to prevent use or disclosure of the Dataset or any information contained therein other than as provided for by this Agreement;
5. To report to Holder any use or disclosure of the Dataset or any part of it not provided for by this Agreement of which User or any Authorized Party becomes aware;
6. Not to use the information contained in the Dataset to identify the individuals whose information is contained in the Dataset, nor to contact them under any circumstances;
7. To obtain approval from the Medical Ethics Committee, as necessary, to use the Dataset;
8. Promptly following the end of the permitted use to return all copies of the Dataset to Holder or destroy them and certify the destruction; or, if User represents and Holder agrees that neither return nor destruction is feasible, to continue to extend the protections of this Agreement to the Dataset. Notwithstanding the above, User may retain one copy of the Dataset for verification purposes only consistent with the obligations and protections agreed to herein;
9. Patient identifying information will not be provided to User. The Dataset may be protected by privacy regulations of a country and/or a Certificate of Confidentiality. User and Holder agree to comply with all applicable statutes, regulations and ethical requirements to protect the identity and privacy of human subjects from whom the data was collected;
10. After termination of this Agreement, the User and Authorized Parties shall no longer be entitled to receive or use information contained in the Dataset;
11. If the User submits a manuscript for publication or otherwise intends to disclose experimental results, User will provide Holder with at least thirty (30) days to review such publication or other public disclosure to protect its confidential or proprietary information. Holder may request an additional thirty (30) days to protect any intellectual property interests. Except with regards to the protection of its confidential or proprietary information, Holder shall have no further editing privileges;
12. To acknowledge the contribution of Holder in all written and/or oral disclosures concerning User’s research using the Dataset, by acknowledgment, in accordance with academic standards and customary practices. Before publication User agrees to provide Holder with copies of public material based on the use of the Dataset. The User agrees to mention at least two of Holder’s scientists as co-author and to acknowledge the Holder and the source of the Material in any publications reporting use of it as is customary in the scientific community

**Article 5 Relief**

User and each Authorized Party agree that the breach or threatened breach of this Agreement may cause irreparable harm to Holder and/or individuals that Holder may not have an adequate remedy at law, and that Holder may therefore be entitled to seek injunctive or other equitable relief to enforce this Agreement.

In the event that Holder becomes aware of any use of the Dataset or any part of it that is not authorized under this Agreement or required by applicable law, Holder may

* Terminate this Agreement upon notice;
* Disqualify (in whole or in part) User and/or any Authorized Parties from receiving protected health information in the future;
* Report the inappropriate use or disclosure to the professional and legal authorities, upon prior notice to User;
* Start any criminal or civil legal action as deemed appropriate, upon prior notice to User.

**Article 6 Liability and Indemnification**

Unless prohibited by law, User assumes all liability for claims and damages which may arise from its use, disclosure and management of de Dataset, except where caused by the negligence or willful misconduct of the Holder..

Each Party shall hold harmless and defend the other Party from and against all claims, losses, liabilities, costs and other expense resulting from or relating to the acts or omissions of a Party in connection with the representations, duties and obligations of a Party under this Agreement. The parties’ respective rights and obligations will under this section survive termination of the Agreement.

**Article 7 Results**

User shall own any and all results of User’s research using the Dataset (“Results”) and shall keep all right, title and interest in the Results including all Intellectual Property Rights.

Holder reserves the right to request from User a copy of any Results arising from the use of the Dataset provided to the User under this Agreement, for its own internal, non-commercial research or educational purposes, on the condition that the Holder complies with restrictions relating to Confidential Information outlined in this Agreement and provided that such right does not in any way impede or infringe the User’s rights to the Results.

**Article 8 Confidentiality***Confidential Information.* The Parties hereto shall treat all proprietary data and other information received from the other Party, including but not limited to business information, technical information and the analyses, evaluations, Data and other information and materials as confidential and proprietary to such other Party (hereinafter referred to as: “**Confidential Information**”).

*Restrictions on disclosure.* The Parties shall take all reasonable steps to maintain the secrecy of the Confidential Information received from the other Party. Moreover, neither Party shall duplicate or use any Confidential Information received from the other Party hereunder for any purpose other than in accordance with this Agreement. In addition, neither Party shall disclose any Confidential Information to any third party that is not specifically authorized in writing by the disclosing Party to receive it. The receiving Party agrees to limit access to the Confidential Information to those employees or consultants who have a need to know in order to carry out the terms of this Agreement. Each Party shall require such employees/consultants to sign non disclosure agreements sufficient for such employee/consultants to comply with terms of confidentiality substantially similar to those outlined in this Agreement. The obligation of confidentiality of the receiving Party shall continue for five (5) years after termination of the Agreement.

*Exceptions.* The Parties agree that the information received from the other Party shall not be deemed Confidential Information to the extent the receiving Party can prove by written record that:

* + 1. it already rightfully had knowledge of such Confidential Information prior to disclosure without obligation of confidentiality to the disclosing Party, or
		2. information was already publicly available or becomes publicly known through no fault of the receiving Party, or
		3. the Confidential Information was already in its possession or is subsequently developed by the receiving Party without use of Confidential Information received from the disclosing Party under this Agreement; or
		4. Confidential Information becomes available to the receiving Party from a third party that is not bound under obligation of confidentiality to the disclosing Party, or
		5. the information is published in accordance with the terms of this Agreement.

*Compulsory disclosure.* Either Party may disclose Confidential Information to the extent required to be disclosed by the receiving Party to comply with applicable mandatory laws, to defend or prosecute litigation or to comply with governmental regulations, provided that the receiving Party takes reasonable and lawful actions to avoid or minimize the extent of such disclosure and informs the disclosing Party promptly of the requirement for such disclosure so that the disclosing Party may take steps to seek to prevent or limit the extent of disclosure. Parties agree to take any actions available to ensure that such competent authorities treat such Confidential Information as confidential.

*Return and/or destruction of Confidential Information.* The Parties agree that such Confidential Information shall remain the property of the disclosing Party, and that all Confidential Information shall be returned to or destroyed by the disclosing Party within thirty (30) days after written request by the disclosing Party. Within thirty (30) days after termination of this Agreement the (remaining) Confidential Information and all copies or extracts thereof shall either be returned or destroyed upon request by the disclosing Party.

**Article 9 Termination of the Agreement**The Agreement shall formally terminate after the User’s completion of the research using the Dataset and within the term mentioned in Article 3.

*Termination for breach.* Either Party may terminate this Agreement at any time if the other Party fails to perform any material covenant, condition, or limitation herein, provided such other Party shall not have remedied (or taken reasonable steps to remedy) its failure within thirty (30) days after receipt of written notice of such failure.

*Other terms of terminations.* Either Party may terminate this Agreement at any time if the other Party becomes bankrupt or insolvent or cease to conduct business in the normal course.

*Survival of terms*. The provisions of this Agreement which by their nature are intended to survive termination or expiry will remain in effect after termination or expiry of this Agreement, including any and all confidential obligations of the Parties. Nothing in this Agreement shall be construed to release either Party of any obligations incurred prior to the effective date of termination.

**Article 10 Miscellaneous**

*Force majeure.* “Force Majeure” shall mean any unforeseeable and exceptional event which is beyond the control of the affected Party and which renders the further performance of that Party's contractual obligations insuperableincluding, but not limited to, Acts of God, regulations or acts of any government authority, war, civil commotion, strikes, or other labour disturbances, epidemics, fire, earthquakes, storms, power failures or other catastrophes of a similar nature. Neither Party shall be deemed to be in default of its contractual obligations whilst performance thereof is prevented by Force Majeure, provided that upon the occurrence of a Force Majeure, the Party suffering therefrom shall immediately give the other Party notice of the occurrence of Force Majeure, stating the nature of the event and providing evidence thereof, likely duration and foreseeable impact upon the other Party.

*Notices.* Any notice to be given under this Agreement shall be sent in writing in Dutch or English and shall be effective when either served by personal delivery, or deposited, postage prepaid, first class airmail registered or certified mail addressed to the Parties at their respective addresses set forth hereunder:

If to Holder:

If to User:

Maastricht University

Faculty of Health, Medicine and Life Sciences

School for Public Health and Primary Care

Att. M. Willems

PO Box 616

6200 MD Maastricht

The Netherlands

*Severability.* Should any part or provision of this Agreement be or become invalid or held unenforceable or in conflict with the law of any jurisdiction, such provision shall be severed and the remainder of this Agreement shall continue in full force and effect to the fullest extent permitted by law. The Parties agree to negotiate in good faith in order to substitute for any invalid or unenforceable provision a valid or enforceable provision, which achieves to the greatest extent possible the economic, legal and commercial objectives of the invalid or unenforceable provision.

*Waiver.* No waiver by either Party, whether express or implied, of any provision of this Agreement or of any breach or default of either Party, shall constitute a continuing waiver of such provisions or a waiver of any other provision of this Agreement.

*Assignment.* Neither this Agreement nor any of the rights and duties created herein may be assigned by User without the prior written consent of Holder, such consent not to be unreasonably withheld.

*Entire agreement and amendments.* This Agreement sets forth the entire understanding and agreement between the Parties as to the subject matter hereof and supersedes and replaces all prior arrangements, discussions and understandings between the Parties relating thereto. This Agreement may be amended only by a written document signed by duly authorized representatives of the Parties.

*Headings.* Headings and titles in this Agreement are for convenience purposes only and shall not in any way influence the construction, performance and enforcement of its provisions.

*Applicable law.* This Agreement shall be interpreted and construed, and the legal relation created herein shall be determined, in accordance with the substantive laws of The Netherlands.

*Dispute resolution.* All disputes arising from or in connection with this Agreement, which cannot be settled amicably, shall be brought exclusively before the competent court in Limburg, the Netherlands.

**Article 11 Disclaimer**Any data delivered pursuant to this Agreement is understood to be experimental in nature.
HOLDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIES FOR A PARTICULAR PURPOSE, OR, THAT THE USE OF DATA WILL NOT INFRINGE ANY PATENT, COPYROGHTS, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

The Parties have caused this Agreement to be executed by their duly authorized representatives in two (2) original copies on the respective dates hereinafter set forth.

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| **[name holder]** | **Maastricht University**  |
|  |  |
| Name: Title: Date: | Name: Title: Date: |

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| **Authorized Parties** |
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| I acknowledge receipt of a copy of this Agreement and, although I am not a party to this Agreement, and confirm that I will abide by its terms insofar as those terms are applicable to me. |
| Name: Title: Date: |
| Name: Title: Date: |
| Name: Title: Date: |

ANNEX 1:

**Description of the research**

The outbreak of COVID-19 has developed into a pandemic, which has globally strained medical resources and caused significant morbidity and mortality. We have developed an algorithm for severity risk assessment and triage at hospital admission. In this project our objective is to externally validate those models on datasets coming form other institutions. The aim is twofold to externally and, if possible, prospectively validate existing models and generate new models generating new hypothesis. Those models are/will be published on the open source data base www;covid19risk.ai.

**Description of the data**

The dataset consists of baseline or sequential clinical, laboratory and CT images of patients with COVID-19

1. **Clinical data:** age, gender, Weight, Length, Smoking, Comorbidity: Hypertension, cardias, pulmonary, renal (acute chronic), diabetes, active cancer (if yes: metastasis, treatment), other comorbidity, Hospital staff, Symptoms at hospital admission: body temperature, dyspnea, interval between first symptoms and hospitalization, Medication at drug admission, Participation to a clinical trial, name of experimental drugs.
2. **Laboratory data:** Lactate Dehydrogenase, Creatine Kinase, Calcium, Urea, C-Reactive Protein, Lymphocytes (%, absolute numbers), Neutrophils, (%, absolute numbers),
3. **Images:** Anonymized-coded CT in DICOM format
4. **Outcome:** Severe disease (see definition herunder), Use of ventilator (if yes how long?), Shock or organ failure, death (if yes how many days after hospitalization), still hospitalized at the moment of data capture

**Definition of severe disease:**

**Severe disease** is defined as: Patients were labelled as having a “severe disease” if at least one of the following criteria were met during hospitalization.

 (1) respiratory distress with respiratory frequency ≥ 30/min;

(2) pulse oximeter oxygen saturation ≤ 93% at rest;

(3) oxygenation index (artery partial pressure of oxygen/inspired oxygen fraction) ≤ 300 mmHg; or

(4) one of the following conditions occurs:

(a) respiratory failure requiring mechanical ventilation;

(b) shock;

(c) ICU admission due to combined organ failure; or

(d) death.

Patients were labelled as having a *“non-severe disease”:*

if none of the above-mentioned criteria were met during the whole hospitalization process until deemed recovered and discharged from the hospital.

**References:**

1. WHO. Coronavirus disease (COVID-19) outbreak. 2020. https://www.who.int/emergencies/diseases/novelcoronavirus-

2019 (accessed Mar 07, 2020).

2. WHO. Coronavirus disease 2019 (COVID-19) Situation Report – 63. 2020.

https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports (accessed Mar 24, 2020).

3. WHO. Events as they happen. 2020. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen (accessed Mar 15, 2020).

4. [www.covid19risk.ai](http://www.covid19risk.ai)

5. Young BE, Ong SWX, Kalimuddin S, et al. Epidemiologic Features and Clinical Course of Patients Infected With SARS-CoV-2 in Singapore. *JAMA* 2020; published online Mar 3. DOI: 10.1001/jama.2020.3204.

6. Guan WJ, Ni ZY, Hu Y, et al. Clinical Characteristics of Coronavirus Disease 2019 in China. *N Engl J Med* 2020; published online Feb 28. DOI: 10.1056/NEJMoa2002032.

7. Deo RC. Machine Learning in Medicine. *Circulation* 2015;132: 1920-30.

8. Deist TM, Dankers FJWM, Valdes G, Wijsman R, Hsu IC, Oberije C, Lustberg T, van Soest J, Hoebers F, Jochems A, El Naqa I, Wee L, Morin O, Raleigh DR, Bots W, Kaanders JH, Belderbos J, Kwint M, Solberg T, Monshouwer R, Bussink J, Dekker A, Lambin P. Machine learning algorithms for outcome prediction in (chemo)radiotherapy: An empirical comparison of classifiers. Med Phys. 2018 Jul;45(7):3449-3459. doi: 10.1002/mp.12967.