Memorandum of Understanding
Investigator Initiated Clinical research

This **Memorandum of Understanding (MOU)** is dated the last date on which it is executed.

BETWEEN THE UNDERSIGNED:

EUSEM Research network *(Institution)* (EUSEM)

AND the party or parties (*Collaborator(s)*) named in Item 2 of Schedule 1.

RECITAL
The parties wish to conduct research and development with a view to achieving agreed research objectives through a research project, the "Research Project," as specified in Item 1 of Schedule 1, on the terms and conditions set out in this Memorandum of Understanding.

IT IS AGREED AS FOLLOWS:

1. RESEARCH PROJECT

Each party agrees to carry out its obligations in accordance with the laws and guidelines that are applicable to their jurisdiction. The collaborator will conduct the study in accordance with the requirements of the Responsible Human Research Guidelines and Laws of the country where they are located.

1.1 Each party must:

(a) bear its own costs under this Memorandum of Understanding; and

(b) obtain and comply with all required authorisations from government agencies and ethics committees which are required for the Research Project; and

(c) not knowingly infringe, and use its best endeavours not to infringe, the Intellectual Property rights of any person in carrying out the Research Project; and

(d) Carry out the Research Project in accordance with all applicable laws of their jurisdiction.

1.2 The parties are committed to appropriate recognition of contributions to invention and exploitation of Intellectual property for the benefit of the communities of the parties.

2. BACKGROUND IP

2.1 Each party warrants that it either owns, or is properly licensed to use, its Background IP and that it has the right to grant the licence in clause 3.2.

2.2 Each party grants to the other party for the Term a royalty free, non-exclusive licence to use that party's Background IP for the purposes of this Memorandum of Understanding only.

2.3 Subject to clause 3.2, no provision of this Memorandum of Understanding affects the rights inherent in the Background IP.

3. LIABILITY AND INSURANCE

3.1 Each party is liable for its acts and omissions in relation to the conduct of the Study.

3.2 Each party must maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study or performing its obligations under this Agreement.

Memorandum of Understanding
Investigator Initiated Clinical research

4. PUBLICATIONS

4.1 The Collaborator, its personnel and the Principal Investigator must not Publish or present any aspect of the Study without the prior written approval of the Institution such approval not to be unreasonably withheld. However, the Collaborator may use and present any information concerning the Study for the purposes of internal training, education, evaluation or discussion without the consent of the Institution.

4.2 The Institution acknowledges that the Collaborator may periodically wish to distribute information releases and announcements regarding the progress of research, including this Study. The Collaborator agrees that they will not release such written or oral material regarding the Study to the news media or a third party without the prior written approval of the Institution, such approval not to be unreasonably withheld.

4.3 The parties agree that publications or presentations of any of the results from the Study will take into account the co-operative nature of the conduct of the Study and the overall objective of increasing public knowledge and shall be in accordance with accepted scientific practice, academic standards and customs and in accordance with the Protocol and with any more specific publication/presentation guidelines developed during the course of the Study, including but not limited to the following:

4.4 If the Study is a Multi-centre Study, the results from a single centre must not be published before the Publication of results from all centres.

4.5 Individuals making a substantial contribution to the Study will be recognised with co-authorship in the publication of results from the Study, unless they elect not to be recognised.

5. STUDY RESULTS AND INTELLECTUAL PROPERTY

5.1 The Collaborator grants to the Institution and its Personnel the right to use the Background IP of the Collaborator and the Study Materials as required to carry out the Study and perform this Agreement. Except for this right, neither the institution nor any of its Personnel acquires any right or interest in any Intellectual Property provided by or on behalf of the collaborator

6. PRIVACY

6.1 Each party must ensure that any Personal Information of Study Participants or Personnel it obtains or holds as a result of the conduct of the Study is collected, stored, used and disclosed by it in accordance with the Relevant Privacy Laws of each parties jurisdiction.

6.2 Each party will promptly report to the other party any unauthorised access to, use or disclosure of Personal Information of Study Participants (“Incident”) of which it becomes aware, and will work with the other party to take reasonable steps to remedy the Incident.

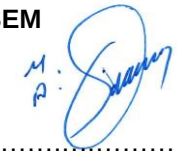
Memorandum of Understanding
Investigator Initiated Clinical research

7. INTERNATIONAL ARBITRATION CLAUSE

This agreement is governed by Belgian law. In the case of disagreement on the construction or performance of this agreement, the Parties shall try to settle their dispute amicably. If the dispute remains, the court with territorial jurisdiction shall be the court of the place of residence of the defendant.

EXECUTED by the Parties on the last date hereinafter appearing:

AUTHORISED REPRESENTATIVE FOR EUSEM



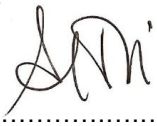
……
Signature of authorised person

Mehmet Akif KARAMERCAN
Name of authorised person (print)

Principal Investigator of EGERS Study
Chair of Research Committee of EUSEM
Position

30 Sep 2020
Date

AUTHORISED REPRESENTATIVE FOR [COLLABORATOR]



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Signature of authorised person

Andrea Fabbri
Name of authorised person (print)

Lead of Italian Research Group
Position

30 Sep 2020
Date

Memorandum of Understanding
Investigator Initiated Clinical research

SCHEDULE 1 – *PROJECT DETAILS*

Item 1	**Research Project**	• ***Project Title: EGERS*** • ***Protocol:*** *Final version 20 September 2020* • *This project is an unfunded collaboration of approximately 70 emergency departments across Europe led by the EUSEM research network. It involves collection of data in relation to determining Epidemiologic and Age Related Characteristics of Geriatric Patients presenting to the ED across Europe and evaluating Early Warning Scoring systems (REMS, MEWS and VIEWS Scores) and determining most suitable Geriatric Emergency Medicine Risk Score regarding hospitalization, ICU admission and in-hospital mortality for patients ≥ 65 years of age* • *(Andrea Fabbri)'s involvement will be provision of non-identifiable patient data collected for the (AUSL Romagna - Forlì) Hospital. Prospective data will be prospectively collected for Geriatric Patients (≥ 65 years of age) presenting to the ED across Europe for consecutive 7 days within 15th* ***October*** **to 15th November in 2020**.
Item 2	**Collaborator(s)** *(Institution names)*	• EUSEM • [**Pronto Soccorso, Medicina d'Urgenza, 118 Presidio Ospedaliero Morgagni-Pierantoni AUSL Romagna, Forlì**]
Item 3	**Term** **Commencement Date** **End Date**	• *["date of last signature"]* • 31 December 2020
Item 4	**Party responsible for obtaining all necessary ethical, administrative and governmental approvals**	*Each party* will be responsible for obtaining all necessary ethical, administrative, governmental and any other approvals are in place to conduct the Research Project *at their sites.*
Item 5	**Background IP**	*Technology, know-how and Confidential Information and all Intellectual Property Rights belonging to or under the control of a Party as at the Commencement Date remain their property. Data is provided by the respective collaborating institutions.*
Item 6	**Study Materials**	*Intellectual Property arising out of the Research Program and in the Research Results shall be:* *EUSEM grants a non-exclusive perpetual licence to the Collaborator to use such material for its own purposes provided that the Collaborator shall not use such material in association with the name of EUSEM or the Collaborator without the prior written consent of EUSEM.*
Item 7	**Dissemination of Results**	*Data will be presented at internal and external educational/ academic meetings and in a publication in a medical journal In all presentations and publications only non-identifiable,*

		pooled results will be presented. *Publication rules:* *All publications and presentations must be approved by the EGERS study steering Committee.* *Any publication will be communicated to local leads at each participating site.* *Authorship:* *The EGERS study Steering Committee will be responsible for the coordination of all articles that will be published.* *The first author will be the one who has made the largest contribution to all aspects of the project, analysis and manuscript preparation.* *Authorship will be decided by members of the EGERS study Steering Committee using ICMJE principles.* *All papers will name the EUSEM Research network study group as an author and all site leads will be listed as members of the group in the acknowledgement section.*
Item 8	**Data Sharing**	*On request, the collaborator will be provided with a summary of its own data and be able to compare it with EGERS study pooled data.* *Data sharing with other collaborators will be considered on a case-by-case basis and may be subject to additional ethics approval.*
Item 9	**Privacy and Confidentiality**	*Data will be collected by collaborators clinicians who would usually have access to the data as part of clinical care.* *Data entry to the online database will be non-identifiable.* *The Database will be password protected and investigators will only have access to their own site data.* *Collaborator Data will be collected and stored according to collaborator research ethics requirements.*

Memorandum of Understanding
Investigator Initiated Clinical research

SCHEDULE 2 – PARTY DETAILS

Institution	**EUSEM**
Authorised Representative: **Name** **Position** **Address** **Telephone** **Facsimile** **E-mail**	This person will sign the agreement Professor Said Laribi EUSEM Research network chair EUSEM office Antwerpsesteenweg 124 B27 B-2630 Aartselaar +32 3870 4616 researchnetwork@eusem.org
Principal Investigator: **Name** **Position** **Address** **Telephone** **Facsimile** **E-mail**	 Professor Mehmet Akif KARAMERCAN Senior Lecturer and Attendant Physician of Emergency Department Gazi University Faculty of Medicine Department of Emergency Medicine Yenimahalle / Ankara, TURKEY Zip Code: 06560 +90 505 3487548 +90 312 2230528 makaramercan@gazi.edu.tr makaramercan@yahoo.com
Other EUSEM staff:	Mr Matthijs Bouwmeester
Research Project obligations:	
Role	EUSEM research network will provide the approved study protocol, data dictionary and data entry instructions for using the online database. It will also facilitate provision of access to approved research personnel to enter data onto the database. EUSEM will manage the online Castor database and provide support for participating sites regarding data entry. Information regarding the Castor database can be found at the following url site: https://www.castoredc.com/clinical-data-management-system/ EUSEM will provide the necessary tools to facilitate control, management and analysis. Report and manuscript preparation will be facilitated by EUSEM in collaboration with the EGERS study steering committee and as outlined in Schedule 1 item 7.
Materials and other in-kind contributions	EUSEM will provide in-kind support for the collaborators regarding any database issues and research project issues. There is no funding for any study obligations assigned to be performed either by collaborator or institution.
Other obligations	EUSEM will follow all local processes for data storage and destruction and will comply with ethics standards in their jurisdictions.

Memorandum of Understanding
Investigator Initiated Clinical research

Collaborator	**Pronto Soccorso, Medicina d'Urgenza, 118 Presidio Ospedaliero Morgagni-Pierantoni AUSL Romagna, Forlì**
Site Principal Investigator: **Name** **Position** **Address** **Telephone** **Facsimile** **E-mail**	 **Andrea Fabbri** **Head of Emergency Unit** **Presidio Ospedaliero Morgagni-Pierantoni, Via Carlo Forlanini 34, 47121 Forlì (FC), Italy** **Telephone +39 3332300698** **Facsimile** **E-mail andrea.fabbri@auslromagna.it**
Other investigators:	• **Barbara Benazzi** • **Marco Cortigiani** • **Alice Morelli**
Research Project obligations:	
Role	The collaborator will enter non-identifiable data onto an on-line database (Castor). The only identifiers will be country and hospital, with the latter used for data verification processes only. Patients will only be identified as case numbers. Local Data collectors will only have access to their own site data. The collaborator will be asked to complete an online survey that will include data on annual patient census.
Materials and other in-kind contributions	The provision of Data to EUSEM is by way of an in-kind contribution by the collaborator and there is no funding for any study obligations assigned to be performed either by collaborator or institution.
Reports	The Collaborator is responsible for providing all required reports to their ethics and governance committees.
Other obligations	The Collaborator will follow all local processes for data storage and destruction and will comply with ethics standards in their jurisdictions.

Appendix 1

- Protocol version 2.3 dated 20 September 2020