eCREAM
enabling Clinical Research
in Emergency and Acute care Medicine

STUDY PROTOCOL

Development of a multipurpose dashboard to monitor the situation of emergency departments

An observational retrospective study

Version 2.2

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eCREAM Coordinating Center
Istituto di Ricerche Farmacologiche Mario Negri IRCCS
Villa Camozzi. via GB Camozzi 3 - 24020 Ranica (Bergamo)

tel. +39 035 4535389 - fax +39 035 4535354 - e-mail: ecream@marionegri.it – Website: ecreamproject.eu

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STUDY CONTACTS

Principal Investigator	Guido Bertolini - Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Italy
Responsible for Coordination of Ethics Committees	Mihaela Matei - ECRIN (European Clinical Research Infrastructure Network)
Scientific Committee	Guido Bertolini, Rita Banzi, Cinzia Colombo - Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Italy Jacek Gorka - Uniwersytet Jagiellonski, Poland Peter Mitro - Univerzita Pavla Jozefa Safarika v Kosiciach, Slovakia Gregor Prosen - Univerzitetni klinicni center Maribor, Slovenia Pankaj Sharma - Ashford and St Peter's hospitals NHS foundation trust, United Kingdom George Notas - Dioikhsh Ygeionomikhs perifereias Krhths, Greece
Technical partners	Astir S.R.L., Italy Fondazione Bruno Kessler (FBK), Italy Orobix Life S.R.L., Italy
Project Management	Giulia Irene Ghilardi, Chiara Pandolfini, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Italy Tel +39 035 4535389/351, +39 02 39014245 giulia_irene.ghilardi@marionegri.it, chiara.pandolfini@marionegri.it
Data management and Statistical analysis	Giovanni Nattino - Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Italy
IT support	Astir S.R.L., Italy
National study contacts	IT: Giulia Irene Ghilardi giulia_irene.ghilardi@marionegri.it Chiara Pandolfini chiara.pandolfini@marionegri.it Istituto di Ricerche Farmacologiche "Mario Negri IRCCS", Italy PL: Jacek Gorka gorkajacek1@gmail.com Uniwersytet Jagiellonski SI: Maja Molan maja.molan@ukc-mb.si Univerzitetni klinicni center Maribor SK: Nikola Jurekova nikola.jurekova@upjs.sk Univerzita Pavla Jozefa Safarika v Kosiciach

UK: Isaac John
isaac.john@nhs.net
Ashford and St Peter's hospitals NHS foundation trust
EL: Aimilia Magkanaraki
amagkanaraki@hc-crete.gr
Dioikhsh Ygeionomikhs perifereias Krhths

SYNOPSIS

BACKGROUND AND RATIONALE	Emergency department (ED) crowding affects most health services in Western countries and is associated with a reduction in the timeliness and effectiveness of care and an increase in patient mortality. Crowding occurs when there is an imbalance between the flow of patients arriving (input), the time taken to assess and treat those already in the ED (throughput), and the flow of patients leaving the ED after treatment (output). Empowering patients, healthcare providers and policymakers by giving them easy access to real-time information on individual EDs that is tailored specifically to each group makes it possible to improve the crowding status and management of the entire flow of patients in the ED. This information spans from priority code assignment criteria to the crowding situation, from waiting times for examinations or specialist consultations to boarding time.
OBJECTIVES OF THE STUDY	To develop dashboards dedicated to three possible types of users: citizens, ED staff, and policymakers. The dashboards will be fed by various hospital information systems automatically, with no need for manual data collections. The source databases will include the ED electronic health record and the laboratory and radiology software. The dashboard will be evaluated for the user-perceived usefulness.
STUDY DESCRIPTION	Observational, multicenter, retrospective study lasting 36 months. A panel of experts for each type of end-user will be involved in dashboard development. The local eCREAM UC2 platform, designed to extract information from the electronic medical records of the EDs, will be installed in each participating hospital in order to automatically collect the data necessary to feed the three dashboards. The data will involve patients who visited the participating centers between July 1 and December 31, 2023. As the establishment and maintenance of a continuous data stream from the participating hospitals is beyond the scope of this study, the data to feed the dashboard will be extracted only once after the end of the data collection period. Information on the EDs' organizational set-up will also be collected. Only the anonymized data needed to feed the three dashboards will be transmitted from the participating centers to the central eCREAM server for the necessary processing. The usefulness of the dashboards will then be assessed by representatives of the three types of end-users through both the use of a questionnaire and participation in in-depth interviews on the usefulness, merits, and shortcomings of the dashboards developed.
ETHICAL CONSIDERATIONS	All the information collected to feed the dashboards will be anonymized and will therefore not fall under the scope of the GDPR. Data collected with questionnaires and interviews will be processed according to the data subjects' consent.
FUNDING	The study is supported by the European Commission (Grant Agreement no. 101057726), UKRI (UK Research and Innovation), and SERI (Swiss State Secretariat for Education, Research and Innovation).

1. INTRODUCTION

1.1 Background and rationale

An emergency department (ED) is a healthcare service that provides the first clinical assessment and treatment to patients with various acute conditions. Timely and high-quality care is essential to fulfill its mandate. These departments, however, are often overwhelmed by the large volume of patients. As a consequence, ED crowding has become a global concern [1,2] and has been correlated to reduced timeliness and effectiveness of care and increased patient mortality [3,4]. Crowding occurs when there is an imbalance between the flow of arriving patients (input), the time taken to assess and treat those already in the ED (throughput), and the flow of patients leaving the ED when their treatment has been completed (output) [5]. All these three components - input, throughput, and output - are closely linked, and an effective program to address ED quality-of-care cannot disregard them and their effect on crowding.

Concerning input, 20% to 30% of patients are brought to the ED by ambulance; the remaining are self-presenting for the vast majority [6]. Notably, non-urgent conditions characterize a high proportion of all ED visits worldwide [7–9], and almost all of these visits involve self-presenting patients. These patients would be most appropriately treated by general practitioners or in services dedicated to non-urgent care [10]. Additionally, when the ED is crowded, these patients typically wait a long time (many hours) before being seen, contributing to ED crowding, and often complain about the waiting time [11]. Increasing the awareness of these patients about the mandate of EDs and the real-time situation of the neighboring emergency departments has the potential to reduce the self-presentation of patients with minor, non-urgent conditions. Such patient empowerment can be achieved through a dashboard informing end-users about the EDs' pre-defined characteristics, such as criteria for assigning the priority code, but also about the crowding levels, the number of patients waiting by priority code, and average waiting time by priority code. A similar dashboard would prompt patients to consider different, more appropriate, or more efficient healthcare services. In addition, in areas where many EDs exist, it would help citizens decide which hospital to go to and when. A real-time dashboard would also help out-of-hospital emergency organizations divert ambulances to the most suitable ED, not simply in terms of the hospital's clinical expertise in relation to the patient's conditions (as is usually the case) but also in terms of the average waiting and treatment times at the EDs (to ensure patients receive the most timely care) and the time to free the ambulance for the next emergency (to minimize the ever-increasing phenomenon of ambulances remaining up to hours in the ED before the patient is unloaded and taken over by ED staff). All this information would contribute to alleviating crowding in EDs.

Concerning throughput, working in the ED requires emergency physicians and nurses to treat many patients at once while maintaining situational awareness of the surroundings. This is especially true for the head of the department, but it also holds for all physicians. It can be crucial, for example, for physicians to know if there is a bottleneck in the flow of the entire patient care process, such as a particularly high average waiting time for radiology reporting or cardiologic consultation. The availability of this information allows countermeasures to be put in place to regain efficiency. Such situational awareness of physicians requires acquiring, processing, integrating, and presenting the appropriate information to prevent these physicians from feeling like they are losing control over the ED.

Something similar can also be said for ED output. Continuous monitoring of the boarding time (i.e., the time between the decision to admit a patient and the time when he or she is actually admitted) and of the wards primarily

involved in the phenomenon improves the control and management of the ED processes and reduces disadvantages and possible harm to the patients.

All this can be achieved through dedicated dashboards automatically fed from various information systems, including the ED electronic health record (EHR) and the laboratory and radiology application software. In addition, appropriate dashboards also enable health policymakers to monitor specific epidemiological phenomena, such as the emergence of certain infectious diseases, in a timely manner.

1.2 The eCREAM project

eCREAM is a European project coordinated by the Laboratory of Clinical Epidemiology at the Istituto di Ricerche Farmacologiche Mario Negri IRCCS (IRFMN). It involves 11 partners in 8 countries (France, Greece, Italy, Poland, Slovakia, Slovenia, Switzerland, and the United Kingdom).

eCREAM is structured in 5 pillars. These are to: 1) develop a natural language processing tool tailored to the typical notes made by emergency physicians and nurses; 2) develop an IT system able to capture data contained in the EHRs in use in different EDs and other administrative databases; 3) develop a new electronic health record for EDs, designed to meet organization, clinical practice, and clinical research needs; 4) take on two different use cases to test and validate the whole system in the field: the assessment of ED propensity to hospitalize patients (use case 1), and the development of a dashboard for citizens, policymakers, and healthcare providers to improve the quality of care in the ED (use case 2); 5) FAIRify (i.e., make data Findable, Accessible, Interoperable, and Re-usable) the established databases for clinicians, researchers, healthcare policymakers, and citizens, respecting the European and national legislations.

eCREAM has been financed by the European Commission under the *Horizon Europe* program (Grant Agreement no. 101057726), UKRI (UK Research and Innovation), and SERI (Swiss State Secretariat for Education, Research and Innovation).

2. **OBJECTIVES OF THE STUDY**

The primary objective of this study, which refers to Use Case 2 of the eCREAM project (eCREAM-UC2), is to develop three different control panels for three different end-users, specifically:

1) Dashboard for citizens
2) Dashboard for healthcare providers
3) Dashboard for healthcare policymakers

The aim is to extract the needed information from heterogeneous sources and to feed the dashboards according to the needs of the end-users. On the whole, for citizens, the dashboard will be designed to empower them to choose the most appropriate ED to attend or to consider a different, more relevant or more efficient, health service; for healthcare providers, the dashboard will provide a clear and immediate picture of the ED situation in terms of patient flow and workflow; for healthcare policymakers, the dashboard will provide the ability to monitor specific phenomena of interest, such as ED crowding level, possible incidence of pre-specified epidemiological phenomena, availability and timeliness of primary and secondary patient transfers, ambulance offload delays, etc.

The secondary objective of this study is to evaluate the usefulness and appropriateness of the dashboards, as perceived by the end-users.

Notably, the developed dashboard will be evaluated on a database retrospectively extracted from the hospitals' information systems, because establishing and maintaining a continuous data stream from the participating hospitals is beyond the scope of this research study. If proven useful, the implementation and distribution of the dashboard will be the subject of future projects.

3. STUDY DESIGN

Observational, multicenter, retrospective study. It is important to emphasize that the purpose of this study is to develop a useful dashboard and not to implement it on real-time data. Thus, even though the dashboard will be fed data that are readily available in the databases of the participating hospitals, it will run on retrospectively extracted data. The suitability of the dashboards (the secondary objective of the study) will be evaluated by means of a survey using a questionnaire and a qualitative assessment via semi-structured interviews.

4. PARTICIPATING CENTERS AND STUDY POPULATION

4.1 Participating centers

The EDs adhering to the eCREAM project will participate in the study, with the exclusion of centers in Greece, as they are currently not using an EHR. Overall, 32 EDs will be included: 18 from Italy, 4 from Poland, 3 each from Slovakia, Slovenia and UK, and 1 from Switzerland. The complete list of participating centers is reported in Annex 1. The centers will not receive any incentive for participating in the study, but expenses incurred for participation will be covered by project funds.

4.2 Study population

All patients who visited the participating EDs during the study period will be eligible for data collection.

Citizens, clinicians, and health policymakers accepting to participate in the dashboard assessment will also provide data for the study.

5. STUDY PLAN AND METHODS

5.1 Development of the dashboards

A panel of experts for each end-user type (patients and citizens, ED physicians and nurses, policymakers and service organizers) will design its own reference dashboard through periodic focus groups and a literature review. The work will be revised by external experts in order to achieve a version that satisfies as many users as possible. These panels will also be responsible for preparing the questionnaire to assess the usefulness of the dashboards.

5.2 Assessment of the dashboards

Representatives of each type of end-user will be involved in evaluating the usefulness of the individual dashboards. More specifically, a group of citizens and patients, a group of emergency physicians and nurses of participating EDs, and a group of health policy and organization managers of the participating centers will be asked

to fill in the prepared questionnaire and to participate in in-depth interviews on the usefulness, advantages and shortcomings of the dashboards developed. These representatives will not be part of the expert panels.

5.3 Data collection

The data required to feed the three dashboards will be collected on all patients who visited the participating EDs between July 1st and December 31st, 2023. Since it is possible that some hospitals faced major changes in the EHR systems during those six months, making it impossible to compare data, we will consider changing the data collection period (in any case, considering 6 continuative months within the 31st December 2023).

The retrospective data extraction from the hospital information systems will start as soon as the local eCREAM UC2 Platform is up and functioning.

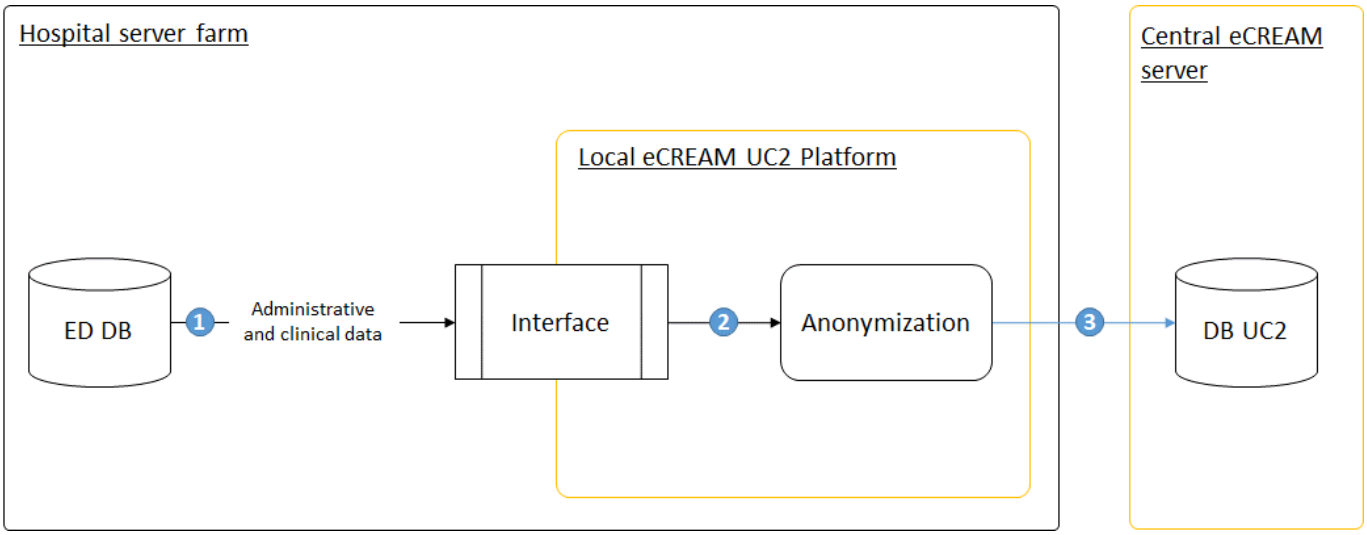
The data will include administrative and clinical information, such as time of arrival at the ED, time of triage and visit, priority code assigned at triage, time of possible hospital admission, and any other data the panels of experts have decided to collect.

Information on the EDs' organizational set-up will also be collected (e.g., the number of available workstations and the capacity to perform certain diagnostic tests).

Finally, once the dashboards are in operation, data from the three panels of experts will be collected through the questionnaires and semi-structured interviews.

5.4 Data processing

The figure below represents the data processing that will be carried out in the context of the eCREAM-UC2 project.



The first data processing step will take place within the participating hospitals' information systems (*Hospital server farm* in the figure), where the *Local eCREAM UC2 Platform* specially developed for the project will be installed. This step consists of extracting all variables needed to feed the dashboards and transmitting them to the *Local eCREAM UC2 platform* through an ad hoc *Interface*. Within this study, the factual transmission of the data will be arranged only once. However, the *Platform* will be designed to be capable of generating, if necessary, multiple data transmissions. This is important to test the possible infrastructure that could be used in future projects if the developed dashboard will be proved useful. The variables will be retained in the local platform as long as necessary

for further processing and subsequent transmission to the *Central eCREAM server*. At the end of the transmission process, the data will be physically deleted.

The *Local eCREAM UC2 platform* will be specifically designed to calculate, from the data received, the indicators that make up the dashboards. Since these indicators are, by definition, aggregate information, such as the time it takes to get the result of a CT scan or the crowding level of the ED, calculating the indicators corresponds to making the data completely anonymous.

In the third step, the anonymous data will be transferred, through secure protocols, to the Central eCREAM server in Milan, Italy, for analysis.

5.5 Study duration

The study will last 36 months: the first 6 months will be used to establish the three panels of experts for the different types of end-users and to develop and refine the dashboards; the following 12 months will be used to install the local eCREAM UC2 Platform in the participating EDs and retrospectively retrieve the required information, checking its quality and making necessary adjustments; 6 months will then be used to put the dashboards into operation; the final 12 months will be used to assess the usefulness of the dashboards through the questionnaires and in-depth interviews, to perform data analyses, and to produce the research reports and disseminate the results.

6. **ADVERSE EVENTS**

As an observational study, participants will be treated according to routine clinical practice. No specific adverse event data collection will therefore be set up.

We will not identify any particular adverse effect related to the qualitative study.

7. **STUDY MONITORING**

While the coordinating center will oversee data collection centrally, in-site study monitoring will not be performed.

8. **ETHICAL CONSIDERATIONS**

8.1 The legal basis for data processing

All information collected to feed the dashboards will be anonymized according to the process described in paragraph 5.4. Anonymization is prescribed, whenever possible, by EU Regulation 2016/679 when data are used for scientific research purposes. More specifically, Article 9, paragraph 2, letter j provides that the data subject's consent is not required when the processing is necessary, among other conditions, for scientific research purposes, in accordance with Article 89(1), based on Union or national law, provided that it is proportionate to the purpose pursued, respects the essence of the right to data protection, and provides for appropriate and specific measures to protect the fundamental rights and interests of the data subject. Paragraph 1 of Article 89, chapter IX, which is recalled here, states that "Processing for archiving purposes in the public interest, scientific or historical research or statistical purposes shall be subject to appropriate safeguards for the rights and freedoms of the data subject, in

accordance with this Regulation. Such safeguards shall ensure that technical and organizational measures are in place, in particular to ensure compliance with the principle of data minimization. Such measures may include pseudonymization, provided that the purposes in question can be achieved in this manner. Where they can be achieved by further processing that does not allow, or no longer allows, the data subject to be identified, those purposes must be achieved in this manner".

As controllers of their own data, the individual centers will be responsible for anonymization according to the process described in paragraph 5.4, through the *Local eCREAM UC2 Platform*. Once anonymized, data will not fall within the scope of the European General Data Protection Regulation (GDPR) 2016/679.

Informed consent will be obtained from the subjects who will be interviewed or have completed the questionnaire to evaluate the dashboards.

8.2 Insurance

Considering the study design and observational approach, no study-specific insurance coverage is required for this study.

8.3 Ethics Committee

This study protocol will be submitted to all participating centers' ethics committees, following the national legislation for observational studies.

8.4 Publication of Data

Publications will be decided on by the Steering Committee (SC), which includes the principal investigator, the co-investigators, and the people responsible for the national coordinating centers. The authors to be reported on the front page will be selected based on their specific contributions to the project. All manuscripts will include an appropriate acknowledgment section, mentioning all investigators who contributed to the study and all supporting agencies, making explicit reference to the European grant that enabled the project to be carried out. Research results will be published irrespective of the findings.

8.5 Data Sharing

The anonymized data derived from this study could be shared for secondary use in the context of research projects.

9. **ROLES OF RESPONSIBILITY**

The Istituto di Ricerche Farmacologiche Mario Negri IRCCS (IRFMN) is responsible for overseeing the activities requested to ensure that the study will be conducted in compliance with the protocol, applicable regulatory requirements, and international guidelines. The PI and scientific committee will have scientific and operational responsibility.

Astir S.R.L. is responsible for installing the *Local eCREAM UC2 Platform* within the information systems of the participating centers. The platform will receive the data from the centers and will transfer it to the study's central server after appropriate processing. Astir could act as a data processor for the individual centers if needed to ensure data processing, including anonymization, as described in paragraph 5.4.

Each country coordinator/national study contact will be responsible for obtaining ethical, regulatory, and legal authorizations in compliance with the European and local provisions, including the GDPR and national data protection regulations.

10. STUDY SUPPORT

The study is supported by the European Commission (Grant Agreement no. 101057726), UKRI (UK Research and Innovation), and SERI (Swiss State Secretariat for Education, Research and Innovation).

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Development of a multipurpose dashboard to monitor the situation of emergency departments

An observational retrospective study

ANNEX 1

List of participating centers and relative PIs

Version 2.2

Ranica, 2 february 2026

eCREAM Coordinating Center
Istituto di Ricerche Farmacologiche Mario Negri IRCCS
Villa Camozzi. via GB Camozzi 3 - 24020 Ranica (Bergamo)

tel. +39 035 4535389 - fax +39 035 4535354 - e-mail: ecream@marionegri.it – Website ecreamproject.eu

ITALY	
Ospedale San Giovanni Bosco, Torino (COORDINATORE)	Dott. Franco Aprà Direttore S.C. Medicina d'Emergenza e Urgenza 2 Ospedale S. Giovanni Bosco, Torino franco.apra@aslcittaditorino.it
Azienda Ospedaliera SS. Antonio e Biagio e C. Arrigo, Alessandria	Dott. Riccardo Boverio Direttore Medicina e Chirurgia d'Accettazione e Urgenza AO SS. Antonio e Biagio e C.Arrigo, Alessandria rboverio@ospedale.al.it
ASST Grande Ospedale Metropolitano Niguarda, Milano	Dott. Nicolò Capsoni Medico Medicina d'urgenza e pronto soccorso Ospedale Metropolitano Niguarda, Milano nicolo.capsoni@gmail.com
Ospedale Maggiore Carlo Alberto Pizzardi, Bologna	Dott. Alessio Bertini Direttore Medicina e Chirurgia d'Accettazione e Urgenza Ospedale Maggiore Carlo Alberto Pizzardi, Bologna alessio.bertini@yahoo.it
Ospedale Santa Maria delle Grazie, Pozzuoli (NA)	Dott. Giovanni Porta Medico Medicina d'urgenza e pronto soccorso Ospedale Santa Maria delle Grazie, Pozzuoli (NA) dottorgiovanniporta@gmail.com
Ospedale San Luigi Gonzaga, Orbassano	Dott.ssa Valeria Caramello Medico Medicina d'urgenza e pronto soccorso Ospedale San Luigi Gonzaga, Orbassano v.caramello@sanluigi.piemonte.it
AOU Policlinico 'G.Rodolico – San Marco', Catania	Dott. Giuseppe Carpinteri Direttore Medicina e Chirurgia d'Accettazione e Urgenza PO Gaspare Rodolico, Catania gicarpinteri@gmail.com
ASST Papa Giovanni XXIII, Bergamo	Dott. Roberto Cosentini Direttore Medicina e Chirurgia d'Accettazione e Urgenza ASST Papa Giovanni XXIII, Bergamo rcosentini@hpg23.it
Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano	Prof. Giorgio Costantino Direttore Medicina e Chirurgia d'Accettazione e Urgenza Ospedale Maggiore Policlinico, Milano giorgio.costantino@policlinico.mi.it
Ospedale degli Infermi, Rivoli	Dott.ssa Paola Molino Medico Medicina d'urgenza e pronto soccorso Ospedale degli Infermi, Rivoli cristinamaria.distefano@aslto3.piemonte.it
Ospedale Sant'Andrea, Vercelli	Dott. Sergio Tartaglia Direttore Medicina e Chirurgia d'Accettazione e Urgenza Ospedale Sant'Andrea, Vercelli srtartaglia@gmail.com
Ospedale Maggiore, Lodi	Dott. Stefano Paglia Direttore Medicina e Chirurgia d'Accettazione e Urgenza Ospedale Maggiore, Lodi Stefano.Paglia@asst-lodi.it

Ospedale di Chivasso	Dott. Paolo Franzese Direttore Medicina e Chirurgia d'Accettazione e Urgenza Ospedale di Chivasso pfranzese@aslto4.piemonte.it
Ospedale Luigi Sacco, Milano	Dott.ssa Anna Maria Brambilla Direttore Medicina d'Urgenza Ospedale Luigi Sacco brambilla.annamaria@asst-fbf-sacco.it
POLAND	
Military Hospital, Kraków	Dr. Jacek Górka Intensive Care and Perioperative Medicine Center Uniwersytet Jagiellonski, Kraków jacek.gorka@uj.edu.pl
University Hospital Kraków, Kraków	Dr. Jacek Górka Intensive Care and Perioperative Medicine Center Uniwersytet Jagiellonski, Kraków jacek.gorka@uj.edu.pl
SLOVENIA	
Univerzitetni klinicni center Maribor, Maribor	Dr. Prosen Gregor Emergency center Univerzitetni klinicni center Maribor, Maribor gregor.prosen@ukc-mb.si
UNITED KINGDOM	
Ashford and St Peter's hospitals NHS foundation trust, Surrey	Prof. Pankaj Sharma Emergency Department Ashford and St Peter's hospitals NHS foundation trust, Surrey pankaj.sharma@rhul.ac.uk
Royal Surrey County Hospital, Guildford	Prof. Pankaj Sharma Emergency Department Ashford and St Peter's hospitals NHS foundation trust, Surrey pankaj.sharma@rhul.ac.uk
Frimley Park Hospital, Camberley	Prof. Pankaj Sharma Emergency Department Ashford and St Peter's hospitals NHS foundation trust, Surrey pankaj.sharma@rhul.ac.uk