# Cross-cHecking to reduce Adverse events Resulting from Medical Errors in the Emergency Department – the CHARMED study

***THIS IS A TRANSLATED VERSION OF THE FRENCH VERSION 1.1, from 8th December 2014***

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# 1. DEFINITIONS

In accordance with definitions and recommendations of the Institute of Medicine, and the french «Direction de la Recherche des Etudes et de la Statistique (DREES) » [1–3], we define the following terms

- Adverse event: an injury that might have resulted from medical management (interventions or lack thereof)

- Near miss: an error with the potential to cause an injury that has been intercepted

As detailed in annex 2, the National Coordination Council for Medication Error Reporting and Prevention classify the severity of a medical error.

An adverse event can be classified from E to I, a near miss from B to D.

# 2. SCIENTIFIC RATIONALE

## *2.1 Context*

Medical errors are a major cause of morbidity and mortality.

Since the Institute of Medicine published in 1999 “To err is human”, medical errors have been a topic of serious concern. In the United States, medical errors could be responsible of 100 000 deaths per year and more than one million injuries. In France, 10 000 deaths and up to 3% of all hospitalizations could be related to medical error. For more than a decade, the rate of harm caused by medical errors has failed to decline although more than a third of them could have been avoided.

Emergency Departments (ED) are usually busy places, where there is a need for quick decision making with potential incomplete information. The simultaneous management of multiple complex patients and the little continuity of care may increase the likelihood of medical errors. Increasing use of ED in western countries, and subsequent elevated risk of overcrowding, led to an increased risk of medical errors. For these reasons, ED are considered as one of the most at risk environment for adverse events resulting from medical errors.

There are sparse data on the rate and severity of adverse events (AE) in the ED. Most of the studies on this topic included passive or self-reporting method for error detection, with

subsequent underestimation of harm. The reported rate of medical errors in the ED vary from 18% to 32%.

Recently, a large prospective study reported that severe medical errors (with the potential to provoke harm) occurred in 10% of visit. We conducted a preliminary study in France, for ED patients that were subsequently admitted, that confirmed these findings, with a rate of medical errors of 55%, including 10% of adverse events

### *2.2 Rationale of the study*

Due to the patient's short length of stay, ED physicians are often alone in their management whereas other specialty can benefit from ward rounds, staff meetings, and multiples handover as patients have longer length of stay.

We conducted a preliminary study that prospectively assessed rates and types of AE resulting from medical errors in the ED, and their associated factors. The only protective factor we found was the participation of more than one physician in the ED management: the involvement of a resident or trainee in the patient care in addition to the senior physician, or a handoff of the patient case in the ED.

This result is consistent with high-risk industrial settings, such as aviation setting, where every important decision, calculation or action needs to be cross checked by a peer. These high risk industries reached a global mortality rate less than 1 per 100 000. Similarly, in the different setting of Operating Rooms, Haynes et al. reported that the implementation of the World Health Organisation check list was associated with a reduction of 40% in the rates of death and complication [12].

Accounting for these results, we sought to evaluate the influence of crosschecking physician decision and management in the ED with a peer. Our hypothesis is that the implementation of a systematic and frequent crosschecking within the ED between colleagues will decrease the rate of medical errors and adverse events.

This randomized trial is the first to implement cross checking in ED setting and evaluate its efficacy for reducing the rate of adverse events in the ED. Thus, it is the first prospective multicenter randomized study to focus on medical errors in French EDs. Traditional approaches included self reporting of medical errors or focused only on medication errors. Our preliminary study and the recent one from Camargo et al. were the first of their kind to prospectively and systematically assess the occurrence of adverse events in the ED [4,11].

Cross checking, a fast procedure, easy to implement even in an overcrowded ED, has been widely adopted in high-risk industries, such as aviation setting, to ensure the highest levels of safety. Thus, this study will also report the feasibility of the implementation of systematic Cross Checking in the ED. The number and diversity of participating centers in France will be a solid argument for future generalization if our hypothesis is confirmed

The settings of ED practice generally include that the care of the patients is left to the decision and action of a sole physician. The results of our preliminary study suggest that exchange of information and shared management are beneficial to the patient and reduce the rate of adverse event. If our hypothesis is demonstrated, the implementation of a systematic and frequent crosschecking of ED physician with each other will help to reduce considerably the morbidity and mortality from medical errors in the ED.

### *2.3 Potential recruitment*

| Centre | Annual census | Monthly recruitment potential | 10 days potential |
|---|---|---|---|
| Pitié-Salpêtrière | 65 000 | 1200 | 400 |
| Saint Antoine | 50 500 | 1150 | 350 |
| Tenon | 45 000 | 840 | 280 |
| Lariboisiere | 76 300 | 1350 | 450 |
| Avicennes | 40 000 | 750 | 250 |
| Grenoble | 48 600 | 900 | 300 |
| TOTAL | 325 000 | 6090 | 2030 |

### *2.4 Declaration that the research will be conducted according to good clinical practice*

I, dr Yonathan Freund, certify that the research i will coordinate will be conducted according this protocol and under good clinical practice guidance.

# 3. Trial objectives

## *3.1 Primary objective*

To evaluate the reduction of the rate of medical error associated with the implementation of systematic cross-checkings between physicians.

## *3.2 Primary endpoint*

The rate of Medical Errors occurring in the ED.

A medical error is defined as

- Adverse Event: an injury that might have resulted from medical management (interventions or lack thereof) (severity E, F, G, H or I according to NCCMERP [13])
- Or « near miss »: an error with the potential to cause an injury that has been intercepted

Serious guidelines violation (local or national), even in the absence of any documented injury, will be considered as adverse events. As previously described, the subsequent adverse events might not clearly appear in the ED settings, hence is considered as a SME

## *3.3 Secondary objectives*

Evaluate the impact of the implementation of cross-checkings on the severity of medical error, and its feasibility.

## *3.4 Secondary endpoint*

Rate of adverse event

Rate of preventable adverse event

Rate of near miss

Severity of medical error

## *3.5 Inclusion criteria*

- Adult patient that visit the ED during one of the recruitment period
- From Monday to friday
- Present in the department between 8H30 and 16H00

### *3.6 Exclusion criteria*

Any patient whose management does not include an emergency physician, including patients that attend to the ED for nurse care, dental emergency, psychiatric emergency, max-fax emergency or surgical referral.

- Patient that attend the ED for follow up visit
- Prisoners
- Non urgent visit defined as patient allocated to a dedicated path of care (ex. out of hours general practitioner, fast track, level 5 (lower) on the severity triage)

As we are evaluating the influence of Cross-Checking, that will occur every two hours, we will exclude all patients whose medical management will be less than one hour in the ED. Duration of medical management will be equal to the delay between first medical contact and discharge time.

## 4. Design of the study

### *4.1 Design*

Cluster randomized cross-over trial (N=6).

A general information on the ongoing study will be provided to patients through individual information notes, and posters in each center.

### *4.2 Duration of the research*

**Total duratio :** 13 months

This duration takes into account the setup of the study in each center, the time required to collect patients' charts, and time required for the two-level review

**Inclusion period:** 2 periods of 10 days in each centre, separated by a one month wash-out interval

**Follow up for each patient:** 7 days

### *4.3 Randomisation*

Each center will be randomised by the methodology and research department on the sequence order of the period. Each period of 10 days (Monday to Friday for two weeks) will be followed by a 4 weeks wash out period, then the alternative strategy, as shown in figure 1

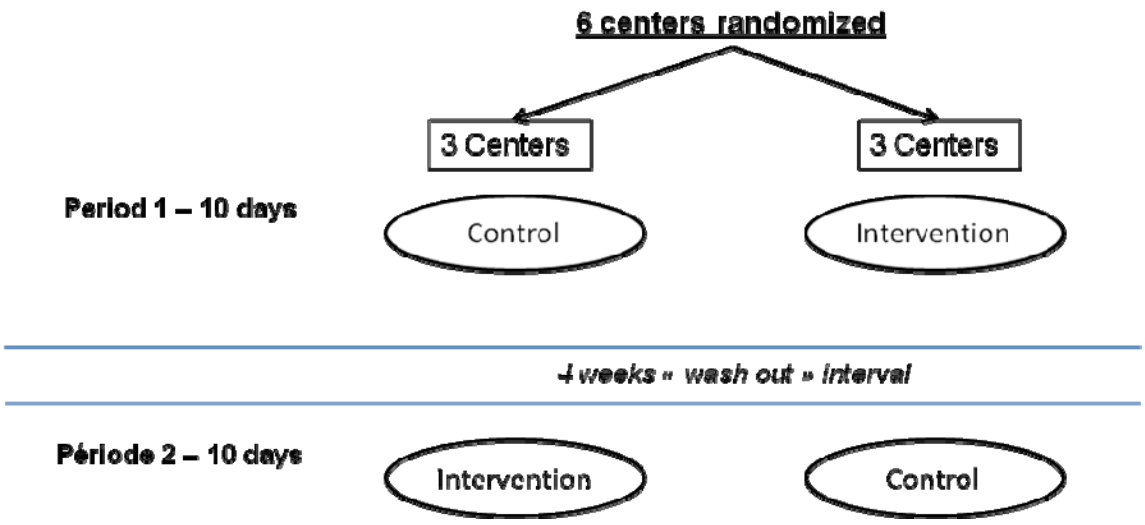


Figure 1: Plan of the research

In both periods, from 9am to 5pm, a CRT will be present in the ED to collect variables on providers and patients.

**In the control period**, usual care and routine management will be provided.

**In the intervention group**, systematic cross-checking will be implemented three times a day from 8:30am to 6:00pm between emergency physicians.

At the end of each period, 14 patients' chart per day in each center will be randomly selected for review. We will use a two-level reviewing method as previously detailed. [20-24]

# 5. EXPERIMENTAL PLAN

## 5.1.1 Different strategies

**In the control period**, usual care and routine management will be provided.

**In the intervention group**, systematic cross-checking will be implemented three times a day from 8:30am to 6:00pm between emergency physicians. The CRT will seek emergency physicians (EP) by pairs for crosschecking. Senior physicians will use peer crosschecking (i.e. crosschecker will also be an emergency senior physician). The CRT will assist the pairing. Each EP will prepare to present all his or her current patients. Patient presentation will be

protocolised, although usual presentation will be sought as this is the presentation method already in place for handover. The crosschecking will occur in the presence of the CRT and in the ED, in any medical office staff room, or cubicle available. The recommended duration of the cross-checkings will be 5 to 10 min.

After each presentation, the comments and advice of the crosschecker will be sought. The CRT will collect duration of the sessions, with the initial and date of birth of any crosschecked patients.

### 5.1.2 Chart selection

The participating centers used an electronic system that collect every ED visits, including severity triage level, time of first contact with physician, time and discharge disposition.

A CRT will select all visits that fulfill the inclusion criteria on an electronic file that will include name, date of brith and time of ED visit. Each patients will be linked to a identifier number $J_n$-000X, n between 1 and 20 corresponding to the day of the visit.. The file with correspondence between name and number will be kept in the local institution in the investigator folder.

The research and methodology department will then randomly select 14 patients each day for analysis.

The randomization list will then be sent to the center, and a CRT will retrieve the complete medical chart pertaining to the ED visit, and if any the discharge summaries of hospital stay. Any new attendance in the ED within the next seven days will be sought. After all charts have been blinded to any mention of date, period and group, Severe Medical Errors will be assessed using a validated two-level reviewing, as express in figure 2.

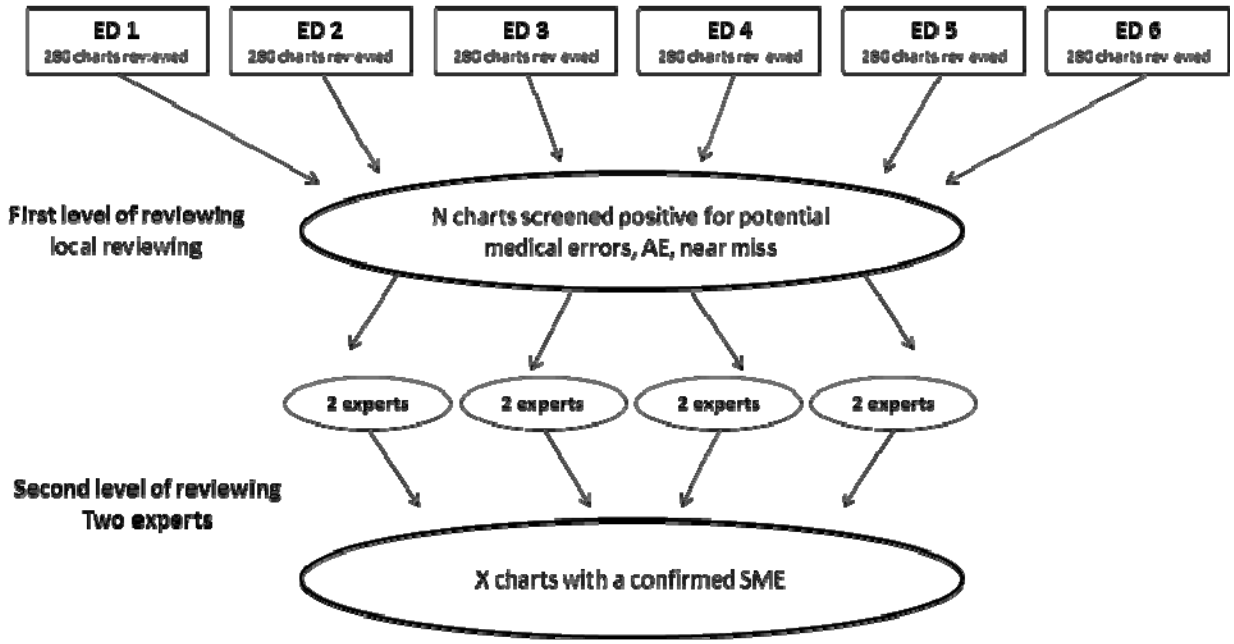


Figure 2: two-level reviewing process for medical error adjudication

### 5.1.3 Screening for medical error – first level

Before the start of the study, all local investigator will be train to chart abstraction for the first level reviewing from the primary investigator. These courses will be held either by teleconference, or direct interview, with the presentation of a syllabi and ghost charts for training. This training has been used in previous study. [20,21]

For all selected patients, a CRT will retrieve the complete medical chart pertaining to the ED visit, and if the patient was admitted into hospital, discharge summaries following hospital discharge. Repeat attendance in the ED within the next seven days will be recorded. All charts will be blinded to date, period and group. Chart review for SME will then be assessed in a validated two phase review process (figure 2).

This first chart review phase will use a an adapted validated questionnaire, derived from the NEDSS study, as a screen to detect adverse events and near misses.

### 5.1.4 Adjudication of the primary endpoint – second level

Any chart that screens positive for at least one item at the first review phase will be sent for external validation and confirmation in the second review phase. These screen-positive charts will be centralized at the methodology and research department and will be independently reviewed by two physicians from a review expert panel in the second chart review phase. This panel will include board-certified emergency physicians and experts in patient safety. Some of the panel members are already trained to chart abstraction and errors validation and classification. The others from the panel will complete a specific training session, with practice chart review and presentation of classification of error in their severity (according to NCCMERP). In cases of disagreement after discussion with the paired reviewer and failure to reach consensus, a third expert, faculty member emergency physician, will be sought to make a final decision. The preventability of any potential adverse event will be reported on a Likert scale as follows: 0) highly unlikely 1) unlikely 2) likely 3) highly likely.

### 5.1.5 Mean to limit bias

**A. Reliability of the first level**

To evaluate whether the first level is reliable, we will randomly select 100 charts that were initially screened negative on the first level, and send them for external reviewing. If the rate of SME is higher than 2% (i.e. upper 95% confidence interval (CI) bound > 5%), all charts will undergo the second level of reviewing to limit selection bias.

B. **Justification of the choice of a cluster cross-over design**

Given the type of intervention in the ED, it is mandatory that it is implemented for a least a whole day in the same center. An individual patient randomisation is unrealistic in this case. We chose to use a cross-over design as a “before-after” design would be subject to bias, especially period effect, as mentioned by L Horwitz about the firs Starmer study on protocolised handoff.[24] With a short implementation period (10 days) and a one month wash out, we may limit the risk of contamination for the centers that will be randomized as strating with the cross-checkings strategy.

# 6. Data management

All data from patients selected for inclusion (280 per center) will be recorded in a e-CRF file. The patient' ref will be : 00N-000M-XX
N=center, M=number of the patient in the center and XX=initials of the patient.
These data will be entered in the e-CRF by a CRT, using the printed medicla charts used for the first level reviewing.
The data regarding the second level reviewing (adjudication of primary and secondary endpoints) will be noted by the experts on a paper CRF, then later recorderd in the e-CRF by a CRT.
Data management will be held by a data manager from URC-Est.

# 7. Statistical analysis

## *7.1 Description of statistical analysis*

We plan no interim analysis.
Patients' characteristics will be described in each group according to the strategy (cross-checkings and control). Characteristics of each center will also be described, as characteristics of the cross-checkings session.
Qualitative data will be reported as number and percentage, and quantitative data as mean and standard deviation or median and interquartile range.

### Analysis of the primary endpoint:

The effect of cross-checking will be estimated through a generalized estimating equation (GEE) model, which will take into account the independence of intracluster observations. Factors associated with SME will also be sought with a GEE Model. Rate of adverse event and near miss will be described and compared between the two periods with a chi square test or Fisher exact test when appropriate.

### *7.2 Nombre prévu de personnes à inclure dans la recherche*

Based on previous literature, we estimate a rate of SME of 10%, with a potential avoidance rate of more than 50% [4,11,24]. With a hypothesis of a 40% reduction in the rate of SME (10% control vs 6 % cross checking), with alpha=0.05 and beta=0.2 and accounting for the fact that the cross-over will counterbalance the cluster's inflation factor, we need to analyze 1584 charts – 140 per period in each center.

The participating center are EDs with an annual census of at least 45 000 visits – more than 120 in mean. We estimated that almost 50% of these visits occurred during the recruitement period. The inclusion target is then highly achievable.

### *7.3 Statistical significance level*

All statistical tests will be two-tailed, and a p less than 0.05 will be required to reject the null hypothesis.

### *7.4 Method to handle missing values*

Missing values will not be computed.

## 8. STEERING COMITTEE

The steering comittee will comprises YF, HG, BR – who conceived the study, the biostatistician (AR) of the methodology department and the coordinator of the methodology (TS)

### 8.1.1 Access to data

In accordance with GCPs:

- the sponsor is responsible for obtaining the permission of all parties involved in the research to guarantee direct access to all locations where the research will be carried out, to the source data, to the source documents and the reports, with the goal of quality control and audit by the sponsor
- the investigators will make available to those in charge of monitoring, quality control and audit relating to the biomedical research the documents and personal data strictly necessary for these controls, in accordance with the legislative and regulatory provisions in force (Articles L.1121-3 and R.5121-13 of the French Public Health Code)

### 8.1.2 Source documents

Source documents are defined as any original document or object that can prove the existence or accuracy of a piece of information or a fact recorded during theresearch. These documents will be kept for 15 years by the investigator or by the hospital in the case of a hospital medical file.

### 8.1.3 Data confidentiality

Those responsible for biomedical research quality control (Article L.1121-3 of the French Public Health Code) will take all necessary precautions to ensure the confidentiality of information about the experimental medications, the research, the research subjects and in particular the identity of the subjects and the results obtained.
These individuals, as well as the investigators themselves, are subject to professional secrecy (in accordance with the conditions set out in Articles 226-13 and 226-14 of the Penal Code).
During or after the biomedical research, the data collected about the research subjects and sent to the sponsor by the investigators (or any other specialised parties) will be made non-identifying.
Under no circumstances should the names and addresses of the subjects involved be shown. The sponsor will ensure that each research subject has given permission in writing for access to personal information about him or her which is strictly necessary for the quality control of the research.

## *8.2 Data processing and storage of documents and data*

### 8.2.1 Identification of the manager and the location(s) for data processing

Data entry will be carried out on electronic media via a web browser by the local research assistant or investigator (CleanWEB, Telemedicines Technologies).

### 8.2.2 Data processing (CNIL, the French Data Protection Authority) in France.

This research falls under the "Méthodologie de référence" (MR-001) according to the provisions of Article 54, paragraph 5 of modified Law No. 78-17 of 6 January 1978 relating to information technology, data files and privacy. This change was approved in a decision made on 5 January 2006. AP-HP, the research sponsor, has signed a commitment to comply with this " Méthodologie de référence ". The processing of personal data for this research falls under the

scope of the provisions of Articles 53 to 61 of the Law of 6 January 1978 relating to information technology, data files and privacy, modified by Law No. 0204-801 of 6 August 2004.

### 8.2.3 Archival

Specific documents for biomedical research will be archived by the investigator and the sponsor for a period of 15 years after the end of the research.

This indexed archival includes, in particular:

A sealed envelope containing the original copies of all information sheets and consent forms signed for all individuals at the centre that participated in the research for the investigator

A copy of all the information notes and consent forms signed for all subjects at the centre that participated in the research for the sponsor

"Research" binders for the Investigator and the sponsor, including:

the successive versions of the protocol (identified by the version no. and date), and the appendices

the CPP favourable opinion

letters of correspondence

the inclusion list or register

the appendices specific to the research

the final research report

The data collection documents

### *8.3 Ownership of the data*

AP-HP is the owner of the data, which cannot be used or disclosed to a third party without its prior approval.

## 9. QUALITY CONTROL AND ASSURANCE

Each biomedical research project managed by AP-HP is ranked from A to D according to the projected risk incurred by research subjects using the classification of biomedical research sponsored by AP-HP.

### *9.1 General organisation*

The sponsor must be responsible for the safety and respect of those subjects who have agreed to participate in the research. The sponsor must implement a quality assurance system to best monitor the conduct of the research in the investigation centres.

For this purpose, the sponsor shall delegate Clinical Research Associates (CRA) whose primary role is to carry out regular follow-up visits at the research locations, after having carried out initial visits.

The objectives of monitoring the research, as defined in the French Good Clinical Practices (BPC section 5.18.1), are to verify that:

- the rights, safety and protection of the research subjects are met
- the data reported is exact, complete and consistent with the source documents
- the research is carried out in accordance with the protocol in force, with the French GCPs and with the legislative and regulatory provisions in force

#### 9.1.1 Strategy for opening the centres

The strategy for opening the centres established for this research is determined using the appropriate monitoring plan.

#### 9.1.2 Level of centre monitoring

In the case of this research, which is considered **A** risk, the appropriate monitoring level has been determined based on the complexity, the impact and the budget for the research. Thus, the sponsor and the coordinating investigator have agreed on the logistic score and impact, resulting in a research monitoring level to be implemented: level **A**

### *9.2 Quality control*

A Clinical Research Associate (CRA) appointed by the sponsor will be responsible for the proper conduct of the research, for collecting and documenting, recording and reporting the data generated in writing, in accordance with the Standard Operating Procedures applied within the DRCD and in accordance with the French Good Clinical Practices as well as with the legislative and regulatory provisions in force.

The investigator and the members of the investigator's team agree to make themselves available during Quality Control visits carried out at regular intervals by the Clinical Research Associate. During these visits, the following elements will be reviewed:

written consent

compliance with the research protocol and with the procedures defined therein

### *9.3 Case Report Form*

All information required according to the protocol must be entered in the case report forms. The data must be collected as and when they are obtained, and clearly recorded in these case report forms. Each missing data item must be coded.

This digital case report form will be implemented in each of the centres thanks to a web-based data collection medium. Investigators will be given a document offering guidance in using this tool.

When the investigators complete the case report via the Internet, the CRA can view the data quickly and remotely. The investigator is responsible for the accuracy, quality and relevance of all the data entered. In addition, the data are immediately verified as they are entered, thanks to consistency checks. Thus, the investigator must validate any changes to the values in the case report form. These modifications will be subject to an audit trail. A justification can be added when applicable, as a comment. A print-out, authenticated (signed and dated) by the investigator, will be requested at the end of theresearch. The investigator must archive a copy of the authenticated document that was delivered to the sponsor.

### *9.4 Management of non-compliances*

Any events that occur as a result of non-compliance, by the investigator or any other individual involved in conducting the research, with the protocol, with the standard operating procedures, with the good clinical practices or with the legislative and regulatory provisions in force must be noted in a declaration of non-compliance addressed to the sponsor. As a first step, major or critical non-compliances will be reviewed and processed by the DRCD's medical coordinator in order to implement the necessary corrective or preventive actions. Next, the non-compliances will be sent to the Quality - Risk Management Division of the DRCD for verification and analysis. These verifications could result in the investigator in charge of the research location in question being asked for information or could lead to compliance or audit visits.

### *9.5 Audits/inspections*

The investigators agree to accept the quality assurance audits carried out by the sponsor as well as the inspections carried out by the competent authorities. All data, documents and reports may be subject to regulatory audits and inspections. Medical secrecy cannot be invoked in opposition to these audits and inspections.

An audit can be carried out at any time by individuals appointed by the sponsor and who are not associated with the research directors. The objective of the audit is to ensure the quality of the research, the validity of the results and compliance with the legislation and regulations in force.

The individuals who lead and monitor the research agree to comply with the sponsor's requirements and with the competent authority regarding research audits or inspections.

The audit may be applicable to all stages of the research, from the development of the protocol to the publication of the results and the organisation of the data used or produced as part of the research.

### *9.6 Primary investigator's commitment to assume responsibility*

Before starting the research, each investigator will give the sponsor’s representative a copy of his/her personal curriculum vitæ, signed and dated, with his/her number in the RPPS (Répertoire Partagé des Professionnels de Santé, Collective Database of Health Professionals).
Each investigator will undertake to comply with the legislation and to carry out the research according to French GCP, adhering to the Declaration of Helsinki terms in force.
The primary investigator at each participating centre will sign a responsibility commitment (standard DRCD document) which will be sent to the sponsor's representative.
The investigators and their employees will sign a delegation of duties form specifying each person's role.

## 10. Legal consideration and ethics

### *10.1 Legal obligation*

Assistance Publique des Hôpitaux de Paris is the sponsor ot this study, as per 2nd alinéa of article L.1121-1 from «  Code de la Santé Publique ». The « Département de la Recherche Clinique et du Développement (DRCD) » represents it.

### *10.2 Sponsor role*

Assistance Publique - Hôpitaux de Paris (AP-HP) is the sponsor of this research and by delegation, the Clinical Research and Development Department (DRCD) carries out the research's missions in accordance with Article L.1121-1 of the French Public Health Code. Assistance Publique - Hôpitaux de Paris reserves the right to halt the research at any time for medical or administrative reasons. In this case, notification will be sent to the investigator.

### 10.2.1 Request for an opinion from the Comité de Protection des Personnes (CPP, ethical review board)

AP-HP, as sponsor, obtains for this biomedical research relating to a medication for human use and prior to starting the research, the favourable opinion of the appropriate CPP, within the scope of its authority and in accordance with the legislative and regulatory provisions in force.

## *10.3 Déclaration CNIL*

This research falls under the 6th january 1978 bill on personal data.
The favourable opinion of CCTIRS and CNIL will be sought prior to the start of the study.

### 10.3.1 Modifications to the research

Any substantial modification to the protocol by the coordinating investigator must be sent to the sponsor for approval. After approval is given, the sponsor must obtain, prior to starting the research, a favourable opinion from the CPP and authorisation from the ANSM within the scope of their respective authorities.
The information sheet and the consent form can be revised if necessary, in particular if there is a substantial modification to the research or if adverse reactions occur.

## *10.4 Information to the patients*

Informations about this research will be displayed in posters in the ED and in the doctors office. According to the 2004-801 law of 6 /08/2004, patients will be informed on their right to oppose the collection and analysis of their personal data.

## *10.5 Final report*

The final report of this research will be drafted by the primary investigator and the steering committee. All co-authors will be mandate to  read, revise, and approve the manuscript.

# 11. SCIENTIFIC COMMITMENT

Chaque médecin participant s'engagera à respecter les obligations de la loi et à mener la recherche selon les B.P.C., en respectant les termes de la déclaration d'Helsinki en vigueur.

Pour ce faire, un exemplaire de l'engagement scientifique (document type DRCD) daté et signé par chaque médecin participant de chaque service clinique d'un centre participant sera remis au représentant du gestionnaire.

# 12. Publication rule

## *12.1 Mention of the affiliation of AP-HP for projects sponsored or managed by AP-HP*

Affiliation of authors from Assistance Publique – Hôpitaux de Paris will include
"AP-HP, hospital, deparment, city, postcode, France"

## *12.2 Mention of the AP-HP manager (DRCD) in the acknowledgements of the text*

"The sponsor was Assistance Publique – Hôpitaux de Paris (Département de la Recherche Clinique et du Développement, Clinical Research and Development Department)"

## *12.3 Mention of the financier in the acknowledgements of the text*

The manuscript will include the following statement :
"The research was funded and sponsored by Assistance Publique – Hôpitaux de Paris (Département de la Recherche Clinique et du Développement; CRC13074). "

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# 14. ANNEX

## *14.1 Annex 1 : Local primary investigator*

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|---|---|---|---|
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## *14.2 Annex 2 : Classification of medical error severity derived from the National Coordinating Council for Medication Error Reporting and Prevention [4] :*

**Severity of near miss and adverse event :**

B Error that did not touch the patient

C Error that touched the patient, with no harm

D Id, required an intervention to avoid harm

E may have contributed or resulted in temporary harm

F Id, and required initial or prolonged hospitalization

G may have contributed to or resulted in permanent patient harm

H required intervention necessary to sustain life

I may have contributed to or resulted in the patient's death