ansm
Agence nationale de sécurité du médicament et des produits de santé

Notification Form of a new event[1] and/or Urgent Safety Measure (USM)[2] concerning clinical investigations on *in vitro* medical device (IV-MD)

One form per New Event / USM

SPECIFY THE TYPE OF NOTIFICATION: ☐ **NEW EVENT** ☐ **NEW EVENT and USM**

DATE OF THE NOTIFICATION :

I. INFORMATION ABOUT APPLICANT

Applicant		Address	
Contact (Surname/Name/Phone Number)			
Courriel			
Name and contact of sponsor: (if different of applicant)			

II. INFORMATION ABOUT THE NEW EVENT

Type of New event	☐ **Procedure to put in place the IV-DM**	☐ **IVDM**	☐ **Others**§
Summary	*Please, specify and transmit the followings (not exhaustive):* - *New Event description* - *Ongoing and planned analysis including detailed schedules* - *An overview and assessment of risk/benefit ratio for ongoing CT* - *Measures (if any) taken following this new event for example substantial modifications (protocol, investigator's brochure…)* - *Other safety information linked to this new event (for example from other drug of the same therapeutic class)*		

§ For Example: measure taken by the sponsor following the data analysis of safety data

III. INFORMATION ABOUT CONCERNED INVESTIGATIONAL CLINICAL TRIAL

Title of clinical trial			
Sponsor Reference Protocol Code (Version and date)		**CPP Contact**	
IDRCB N°		**EUDAMED N°**	
Type of Clinical trial	☐ **First In Human**	☐ **Healthy volunteers**	
Version and date of last Annual Safety Report (ASR)			
Number of included subjects	**in France**	**Out of France**	
Number of subjects receiving treatment	**in France**	**Out of France**	
Number of subjects planned to be included	**in France**	**Out of France**	
Is there an independent Data Safety Monitoring Board (DSMB)?		☐ Yes	☐ No
If any, please submit the minutes of the last meeting and, if available, please provide the opinion of DSMB about this new event :			

Urgent Safety Measure (USM) taken by the sponsor/investigator	☐ Yes ☐ No
If yes, detail the measures taken: If not, justify,	
Substantial Modification planned following this new event:	☐ Yes ☐ No
If yes, precise the planned date of submission:	

IV. INFORMATION ON THE IV-DM

CE Marking	☐ Yes ☐ No
Unique Device Identifier (UDI) system	
Manufacturer	
Class of the device	

Precise the current reference document for the qualification of serious expected/unexpected undesirable adverse effects (Article 1 of the 3rd March 2017 decision of Ansm concerning the format, content and modalities of undesirable effects and new events notification for the research with a MD or a IV-DM)

☐ **Investigator's Brochure (IB) - version yyyy, section xxxx :**

☐ **Notice to the user - version xxx :**

☐ **Protocol - version yyyy, section xxxx :**

[1]**New event** as defined in article R. 1123-46 of the French Public Health Code: Any new data that may lead to a re-assessment of the benefit/risk ratio of the clinical trial or the investigational medicinal product (IMP), to modifications of the use of the IMP or the conduct of the trial or modifications of documents regarding the trial or to the suspension or termination of the clinical trial or to modify the protocol of the trial concerned or other similar trials. For a first in man study conducted in healthy volunteers: any serious adverse reaction (SAR) of the IMP is considered to be a new event

[2]**Urgent safety measures** as defined in articles L. 1123.10 and R. 1123-62 of the French Public Health Code: In case of any SUSAR or new event that is likely to affect the safety of the subjects, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects against immediate hazard