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| Notification Form of a new event1 and/or Urgent Safety Measure (USM)2 concerning clinical trials on medicinal products |



***One form per New Event / USM***

sPECIFY the TYpe of notification:  New Event  NEW EVENT and USM

DATE: Cliquez ici pour entrer une date.

1. Information about applicant

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Applicant | |  | Address |  |
| Contact | Surname/ Name |  |
| Phone Number |  |
| Email |  |

## INFORMATION about new event / Urgent Safety Measure (USM)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Type of New event | Quality data | Non Clinical data | Clinical data | | | 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 brochure…)* * Other safety information linked to this new event (for example from other drug of the same therapeutic class) | | | | | |
| **Urgent Safety Measure (USM) taken by the sponsor/investigator**  **If yes, answer to the following points:** | | | | Yes | No | |
| **Suspension of clinical trial (or clinical trials)**  If yes, specify: | | | | Yes | No | |
| Suspension of inclusion | | | | Yes | No | |
| Suspension of investigational medicinal product administration | | | | Yes | No | |
| **Protocol modification** | | | | Yes | No | |
| **Investigator brochure (BI)** | | | | Yes | No | |
| **Dear investigator letter (DIL)** | | | | Yes | No | |
| **Are there any others foreseen measures?** | | | | Yes | No | |
| If yes, specify nature and timing : | | | | | | |

## INFORMATION about Concerned clinical trials

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Title of clinical trial |  | | | | | | | | |
| Name of the sponsor (if different from applicant) |  | | | | | | | | |
| Phase |  | EudraCT Number |  | | | Protocol reference  (Version and date) | |  | |
| French Ethics Committee: Contact information | *(Name, phone number and email)* | | | | | | | | |
| Type of Clinical trial | First in Human (FIH) | |  | Blood-derived products | | |  | | |
| Healthy volunteers | |  | Gene therapy medicinal products | | |  | | |
| Early Clinical trials3  (excluding FIH) | |  | Cell therapy medicinal products and tissue engineered products | | |  | | |
| Complex design clinical trial4 | |  | Prophylactic vaccine | | |  | | |
| First in Class (FIC) | |  | Vulnerable population | | | Children (< 18 years)  elderly (> 65 years)  Pregnant/breastfeeding  Others, specify | | |
| Number of included subjects | In France: | | In Europe  (Out of France): | | | | Out of Europe: | | |
| Number of subjects receiving treatment | In France: | | In Europe  (Out of France): | | | | Out of Europe: | | |
| Number of subjects planned to be included | In France: | | In Europe  (Out of France): | | | | Out of Europe: | | |
| **Is there an independent Data Safety Monitoring Board (DSMB)?** | | | | | | | Yes | | No |
| **Are there minutes about the DSMB position regarding the new event?** | | | | | | | 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 : | | | | | | | | | |
| Version and period of last Annual Safety Report (ASR/DSUR) |  | | | | | | | | |
| Current Reference Safety Information (RSI) | IB (Date, version) :    Section : | | | | Summary of Product Characteristics (SmPC),  *(Date and version)* | | | | |
|  | | | | | | | | | |

Other clinical trial if concerned:

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## INFORMATION on Investigation MEDICINAL Product(s)

|  |  |
| --- | --- |
| Code |  |
| INN |  |
| Name of the medicinal product |  |
| Therapeutic class |  |

Other medicinal product (*for example in case of drug combination)*

|  |  |
| --- | --- |
| Code |  |
| INN |  |
| Name of the medicinal product |  |
| Therapeutic class |  |

## Annex

1New 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

**2Urgent safety measures** as defined in articles L. 1123.10 and R. 1123-62 of the French Public Health Code and in the detailed guidance CT-1: 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.

**3Early Clinical trials**: Clinical trials conducted on healthy volunteers or patients that generate initial knowledges in humans on tolerability, safety, pharmacokinetics and pharmacodynamics of an investigational medicinal product. These are phase 1, or phase 1-2 clinical trials (if the phase 1 takes place on the French territory).

4Clinical trial with complex design: Clinical trial with multiple independent sub-protocols s (e.g « basket, umbrella, matrix » trials)