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# Important Medical Events (IME) - Relative Benefits of In-house vs Standard Lists

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## Rationale

The European Clinical Trials Directive 2001/20/CE on investigational medicinal products was transposed in France to ALL interventional clinical trials (clinical trials on medicinal products, on medical devices ; pathophysiology studies)

## Rationale

The HCL sponsor 165 “investigator-driven” clinical trials:

50 % Clinical trials on medicinal products

30% Other therapeutic trials (e.g. radiotherapy, surgery, transplantation, physical therapy, psychotherapy); pathophysiology studies, diagnostic studies, nutrition studies

20% Clinical trials on medical devices

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→ *The sponsor must assess seriousness of the adverse events but also have a reference document for assessing expectedness of all reactions*

## The use of IME terms list for assessing seriousness

For all interventional clinical trials, the standard IME list is used to decide whether the event is medically serious or not.

In practice:

Call from trial site to discuss with the vigilance unit of the seriousness of an event that does NOT meet the usual regulatory serious criteria (life threatening/fatal, hospitalisation, requiring intervention, etc)

→ Standard IME terms list (in: to be reported as a SAE; out: to be reported in the CRF)

NB: the current version of the IME list at the time of the serious adverse event is used.

## The use of IME terms list for expectedness

The sponsor has to assess the expectedness of all serious adverse reactions with the reference document:

For clinical trials on medicinal products → IB or SmPC

But, for medical device trials (as the SARs on the instruction notice are rarely reported) or other therapeutic trials, the reference document is the protocol

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## The use of IME terms list for expectedness

For medical device and other therapeutic studies, the HCL vigilance unit reviews the safety part of each protocol and uses the IME list:

- ✓ To help to build the reference document (protocol) and to identify the expected serious adverse reaction(s)

*Safety part of the protocol to indicate the expected serious adverse reactions of the study (medical device and physiological studies only)*

*List of IME terms selected by the investigator*

**12. EVENEMENTS INDESIRABLES GRAVES**

**A. Définition générale**

Est défini comme Evénement Indésirable Grave (EIG) toute manifestation nocive qui, quelle que soit la dose :

- Entraîne le décès
- Met en jeu le pronostic vital
- Entraîne l'hospitalisation ou une prolongation d'hospitalisation
- Entraîne une invalidité ou une incapacité permanente ou significative
- Est une anomalie congénitale
- Est considéré comme un événement médicalement important

**B. Effets indésirables graves attendus dans le cadre de cette étude**

Les effets indésirables graves attendus de cette recherche liés à la pathologie des patients, à l'angioplastie coronaire et aux examens réalisés dans le protocole sont listés en annexe 5

**ANNEXE 5 : LISTE DES EFFETS INDESIRABLES GRAVES ATTENDUS**

(Important Medical Event terms (IME) list based on MedDRA version 13.1).

PT_NAME	SOC_NAME
Atrioventricular block complete	Cardiac disorders
Cardiac arrest	Cardiac disorders
Cardiac failure	Cardiac disorders
Cardiac failure acute	Cardiac disorders
Cardiogenic shock	Cardiac disorders
Cardio-respiratory arrest	Cardiac disorders
Cardio-respiratory distress	Cardiac disorders
Ventricular arrhythmia	Cardiac disorders
Ventricular failure	Cardiac disorders
Ventricular fibrillation	Cardiac disorders
Ventricular tachyarrhythmia	Cardiac disorders
Ventricular tachycardia	Cardiac disorders
Death	General disorders and administration site conditions
Sudden death	General disorders and administration site conditions

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## The use of IME terms list for expectedness

In practice:

- ✓ Discussion and selection of IME terms from the list with the Principal Investigator → identification of critical SOCs then PT terms (CS and ES)
- ✓ All the SAR received by the sponsor that are not in the list are assessed as being unexpected and submitted to expedited reporting
- ✓ Usually, the same version of the IME list is kept for the entire course of the study; if not, the protocol is amended

## Advantages & Disadvantages

- 👍 Good opportunity to initiate the discussion on the safety of the trial
- 👍 Facilitates the sponsor's assessment of expectedness for non investigational medicinal product studies
- 👍 The hierarchy is really useful for the investigator (not so familiar with MedDRA)
- 👎 The use of the IME list can limit the judgment of the investigator
- 👎 10 000 terms to review
- 👎 Only few medical device terms

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*Thank you for  
your attention*