

Standard IME vs home grown serious lists

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Home-grown serious list (GSK)

- Physicians' opinions vary in different data entry sites
- Initially had agreed medical concepts (since mid 1990s)
- Translated to MedDRA LLTs (in 2003)
- Serious LLTs are loaded into pharmacovigilance database
- *Does NOT apply to clinical trials (those have investigators' serious assessments)*



Applications in GSK

- Fully automated in safety database
 - Linked to event code: assesses each event for spontaneous, post marketing and selected clinical reports (where first source is literature).
 - A serious event in case without the usual regulatory serious criteria results in upgrading for expedited reporting
- Automated event selection
 - in Periodic Safety Update Report (PSUR) tabulations (from safety database)
 - Prioritising for signal detection



Event details on database

Summary	Event Details	Local
Event Descrip	VENTRICULAR TACHYCARDIA	Receipt
Verbatim	Pref Term Ventricular tachycardia	SOC Cardiac d
Event Type	E Event	Group 1
Onset Date and Time	Time to Onset	Time to Onset since last
Outcome	Outcome Date and Time	Duration
U Unknown		
Action Taken	Relationship to suspect medication	U Unknown
<input type="checkbox"/> Did Event Reoccur on Rechallenge		
Frequency	Patient withdrawn from Clinical Study	
Severity/Toxicity	Event related to participation in study	
Serious Assess.	Event obtained from Record of Death	
Y Yes	AE Subtype	
Automatic	Study Phase	



Why use LLT, not PT

- LLT permits finer discrimination
- PT *Gout*
 - LLTs Articular gout, Gout, **Gout acute, Gout aggravated, Gout attack, Gout flare**, Gout unspecified, Retrocedent gout, Secondary gout
 - Gout is chronic, not necessarily drug induced.
 - Acute situations may result from drug interactions or lack of efficacy. Therefore **4 red LLTs** are on the serious list.



Advantages of home-grown list

- Can be tailored to product and/or patient population (CIOMS V)
- Smaller and more targeted list (than standard IMEs) is more discriminating for safety signal detection
- Easily changed to suit specific requirements (e.g. Device reporting regulations)



Disadvantages of home-grown list

- Not easy task to maintain a list that suits most drugs/therapeutic indications, especially if portfolio is varied
- Has to be maintained (MedDRA versions, ad hoc queries)



Discussion /Questions

