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Present Situation

Method	Frequency of ADR					
	> 1/10 - 100	1/100- 1/1000	1/1000 – 1/5000	1/5000 – 1/10000	1/10000 – 1/50000	< 1/50000
(-) without relevance (+) possible supportive (++) supportive						
Spontaneous reports	+	++	++	++	++	-
Intensives Monitoring	+	++	++	+	-	-
Prescription Event Monitoring	+	++	++	+	-	-
Case-controll- Studies	-	+	++	++	-	-
PMS Studies	+	++	+	-	-	-
Large Data Resources (+record linkage)	-	++	++	+	+	-
Clinical trials	++	+	-	-	-	-

Methodes for detection of ADR incidence, Meyboom, Drug safety 1997



Pharmacovigilance

Detection of risks

Number of cases needed to detect the difference of an increased risk in comparison to background Incidence.

Background Rate	RR to be Detected (relation of exposed to not exposed is 1:1)			
	2	5	10	20
1/100	2,319	285	100	40
1/1000	23,518	2,935	1,060	451
1/10,000	235,500	29,433	10,656	4,562
1/100,000	2,355,235	294,411	106,615	45,666

