Cardiac failure (SMQ)

"acute left ventricular failure" "acute pulmonary oedema" "acute right ventricular failure" "cardiac asthma" "cardiac failure" "cardiac failure acute" "cardiac failure chronic" "cardiac failure congestive" "cardiac failure high output" "cardiogenic shock" "cardiohepatic syndrome" "cardiopulmonary failure" "cardiorenal syndrome" "chronic left ventricular failure" "chronic right ventricular failure" "congestive hepatopathy" "cor pulmonale" "cor pulmonale acute" "cor pulmonale chronic" "ejection fraction decreased" "hepatojugular reflux" "left ventricular failure" "low cardiac output syndrome" "neonatal cardiac failure" "obstructive shock" "pulmonary oedema" "pulmonary oedema neonatal" "right ventricular ejection fraction decreased" "right ventricular failure" "ventricular failure"

The algorithms of ROR

Table 1 ROR method in disproportionality analysis

Project	Specific Adverse Event Reports	Other Adverse Event Reports	Total
Drug 1 combined with Drug 2	a	b	a+b
Drug 1 without Drug 2	c	d	c+d
Total	a+c	b+d	n=a+b+c+d

a represents the number of reports in which **Drug 1 combined with Drug 2** was associated with a specific adverse event.

b represents the number of reports in which **Drug 1 combined with Drug 2** was associated with other adverse events.

c represents the number of reports in which **Drug 1 without Drug 2** was associated with the specific adverse event.

d represents the number of reports in which **Drug 1 without Drug 2** was associated with other adverse events.

n represents the total number of adverse event reports associated with Drug 1.

$$ROR = \frac{(a/c)}{b/d} = \frac{ad}{bc}$$

$$95\%\ CI = e^{\ln(ROR)\pm 1.96\sqrt{\frac{1}{a}+\frac{1}{b}+\frac{1}{c}+\frac{1}{d}}}$$

The algorithms of Ω shrinkage

Table 2 The algorithms of Ω shrinkage

Project	Target AE	All other AEs	Total
drug 1 and drug 2	n111	n110	n11+
drug 1 without drug 2	n101	n100	n10+
drug 2 without drug 1	n011	n010	n01+
Neither drug 1 or drug 2	n001	n000	n00+
Total	n++1	n++0	n+++

$$\Omega = \log_2\left(\frac{n_{111}+0.5}{E_{111}+0.5}\right)$$

$$\Omega_{025} = \Omega - \frac{\varphi(0.975)}{\log(2)\sqrt{n_{111}}}$$

The detection criterion for Ω:

$$\Omega_{025} > 0$$