The MOdified NARanjo Causality Scale for ICSRs (MONARCSi): A Decision Support Tool for Safety Scientists
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Online Resource 12 Training Dataset results for the MONARCSi model compared to company causality ratings (N = 512 ICSR drug-event pairs)

		MONARCSi Causality Determination		
		Yes	No	Totals
Company Causality Determination Using Global Introspection	Yes	91	57	148
	No	27	337	364
	Totals	118	394	512

Online Resource 13 MONARCSi Training Dataset performance metrics compared with clinical judgment using global introspection as reference (N = 512 ICSR drug-event pairs)

Performance Metric	Value
Sensitivity % Positive Agreement	61.5%
Specificity % Negative Agreement	92.6%
Positive Predictive Value (Precision) Proportion of true "related" out of all classified "related"	77.1%
Negative Predictive Value Proportion of true "unrelated" out of all classified "unrelated"	85.5%
Gwet AC1 Kappa Score Inter-rater agreement with Ground Truth	73.3%
F-Score (F1) Harmonic mean between precision and recall	68.4.0%

Online Resource 14 Validation Dataset results for the MONARCSi model compared to company causality ratings (N= 279 ICSR drug-event pairs)

		MONARCSi Causality Determination		
		Yes	No	Totals
Company Causality Determination Using Global Introspection	Yes	56	30	86
	No	14	179	193
	Totals	70	209	279

Online Resource 15 MONARCSi Validation Dataset performance metrics compared with clinical judgment using global introspection as reference (N= 279 ICSR drug-event pairs)

Performance Metric	Value
Sensitivity % Positive Agreement	65.1%
Specificity % Negative Agreement	92.7%
Positive Predictive Value (Precision) Proportion of true "related" out of all classified "related"	80.0%
Negative Predictive Value Proportion of true "unrelated" out of all classified "unrelated"	85.6%
Gwet AC1 Kappa Score Inter-rater agreement with Ground Truth	73.6%
F-Score (F1) Harmonic mean between precision and recall	71.8%