The MOdified NARanjo Causality Scale for ICSRs (MONARCSi): A Decision Support Tool for Safety Scientists

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Online Resource 10 Aggregate feature weighting for each MONARCSi Feature across therapeutic area and geography for the presence (confirmatory evidence) and absence (disconfirmatory evidence)

1. MONARCSi Feature 1: Significant Safety Event
   a. MONARCSi Feature 1: Significant Safety Event – confirmatory

   ![Confirmatory Feature Weighting Graph]

   Region
   - Asia-Pacific: 3.83 ± 1 SD
   - Europe: 3.68 ± 1 SD
   - North America: 3.49 ± 1 SD

   Safety Science Work Area
   - Immunology: 3.80 ± 1 SD
   - Early Development: 3.18 ± 1 SD
   - Mature Products: 3.67 ± 1 SD
   - Oncology: 3.56 ± 1 SD

   b. MONARCSi Feature 1: Significant Safety Event - disconfirmatory

   ![Disconfirmatory Feature Weighting Graph]

   Region
   - Asia-Pacific: 1.50 ± 1 SD
   - Europe: 1.18 ± 1 SD
   - North America: 1.22 ± 1 SD

   Safety Science Work Area
   - Immunology: 1.25 ± 1 SD
   - Early Development: 0.36 ± 1 SD
   - Mature Products: 0.67 ± 1 SD
   - Oncology: 1.80 ± 1 SD
2. MONARCSi Feature 2: Previous Association

   a. MONARCSi Feature 2: Previous Association – confirmatory

   ![Confirmatory Association Diagram]

   b. MONARCSi Feature 2: Previous Association – disconfirmatory

   ![Disconfirmatory Association Diagram]

3. MONARCSi Feature 3: Temporality

   a. MONARCSi Feature 3: Temporality – confirmatory

   ![Confirmatory Temporality Diagram]
b. MONARCSi Feature 3: Temporality – disconfirmatory

4. MONARCSi Feature 4: Mechanism of Action

a. MONARCSi Feature 4: Mechanism of Action – confirmatory

b. MONARCSi Feature 4: Mechanism of Action – disconfirmatory
5. MONARCSi Feature 5: De-Challenge

a. MONARCSi Feature 5: De-Challenge – confirmatory

![Graph showing mean feature weights across regions and work areas.]

b. MONARCSi Feature 5: De-challenge – disconfirmatory

![Graph showing mean feature weights across regions and work areas.]

6. MONARCSi Feature 6: Re-Challenge

a. MONARCSi Feature 6: Re-Challenge – confirmatory

![Graph showing mean feature weights across regions and work areas.]

b. MONARCSi Feature 6: Re-Challenge – disconfirmatory

![Graph showing mean feature weights across regions and work areas for Re-Challenge disconfirmatory feature.]

7. MONARCSi Feature 7: Dose Response

a. MONARCSi Feature 7: Dose Response – confirmatory

![Graph showing mean feature weights across regions and work areas for Dose Response confirmatory feature.]

b. MONARCSi Feature 7: Dose Response – disconfirmatory

![Graph showing mean feature weights across regions and work areas for Dose Response disconfirmatory feature.]

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8. MONARCSi Feature 8: Experimental Data

a. MONARCSi Feature 8: Experimental Data – confirmatory

b. MONARCSi Feature 8: Experimental Data – disconfirmatory

9. MONARCSi Feature 9: Confounding Factors

a. MONARCSi Feature 9: Confounding Factors – confirmatory
b. MONARCSi Feature 9: Confounding Factors – disconfirmatory