The **M**Odified **N**ARanjo **C**ausality **S**cale for ICSRs (MONARCSi): A Decision Support Tool for Safety Scientists

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**Online Resource 1**

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**Data Extract Overview**

- **Extract:** Oracle Database Table Query
- **Scope:** Clinical ICSRs, most recent approved version
- **Dates:** 1 January – 30 September 2016

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**Unique ICSRs**

- Total: 8831
- Limited to 25 ICSRs per Safety Scientists: 2017
- Limited to Roche Products: 1304
  - 75% of the data (978 of the 1304 drug/event pairs) was used for training
  - 25% of the data (326 of the 1304 drug/event pairs) were held for testing
- Unique Protocols: 77
- Unique Reviewers: 38
- Total: 3802