

Dynamic SMQ Search for Safety Signal Detection Using Spotfire

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The Background

- Standardised MedDRA Queries (SMQs) are groupings of terms from one or more MedDRA System Organ Classes (SOCs) related to defined medical condition or area of interest.
- SMQ use is recommended as the powerful search strategy to retrieve potential cases of interest for early detection and evaluation of emerging safety signals in clinical development.

The Challenge

- Without SMQs, safety scientists either rely on manual review with non-standardised groups of terms, which is prone to error, or cross-functional programming support of data retrieval, which is time consuming with back-and-forth change requests and communication.
- Providing a powerful, user-friendly platform to enable effective SMQ search becomes vital in supporting real-time safety signal monitoring in pharmacovigilance.

The Mission

We explored an **interactive approach to SMQ search in Spotfire** and developed a **data exploration tool** that empowers safety scientists to conduct self-service review based on any SMQ(s) of interest to support ongoing safety signal detection and data analysis.

Implementation Considerations

How to manage all SMQs in Spotfire?

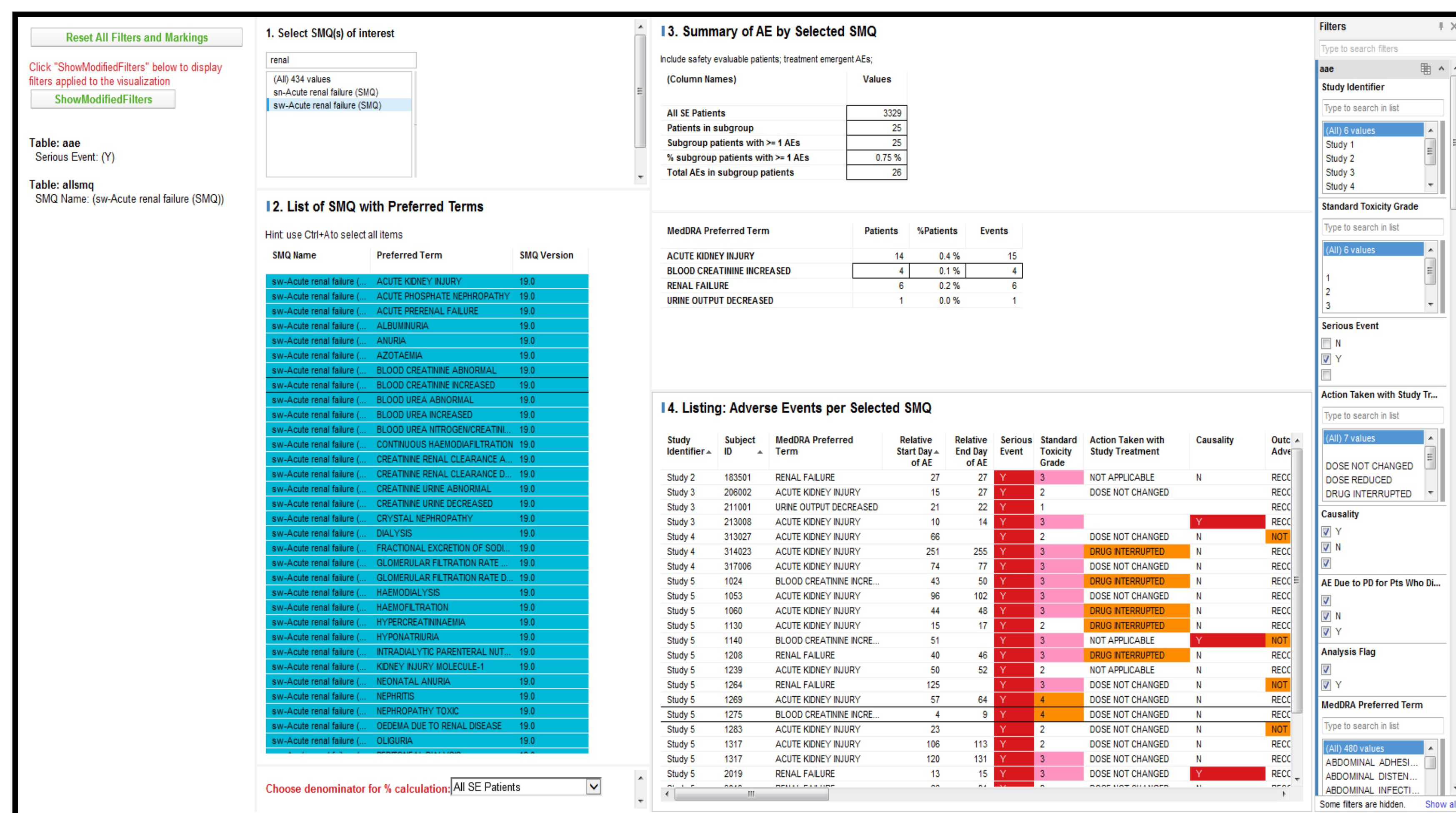
- **Master SMQ** to combine all SMQs into one dataset

How to address MedDRA versioning update?

- One master SMQ for each MedDRA version
- Use of the **same MedDRA version** between SMQs and clinical database
- Automated configuration of SMQ update

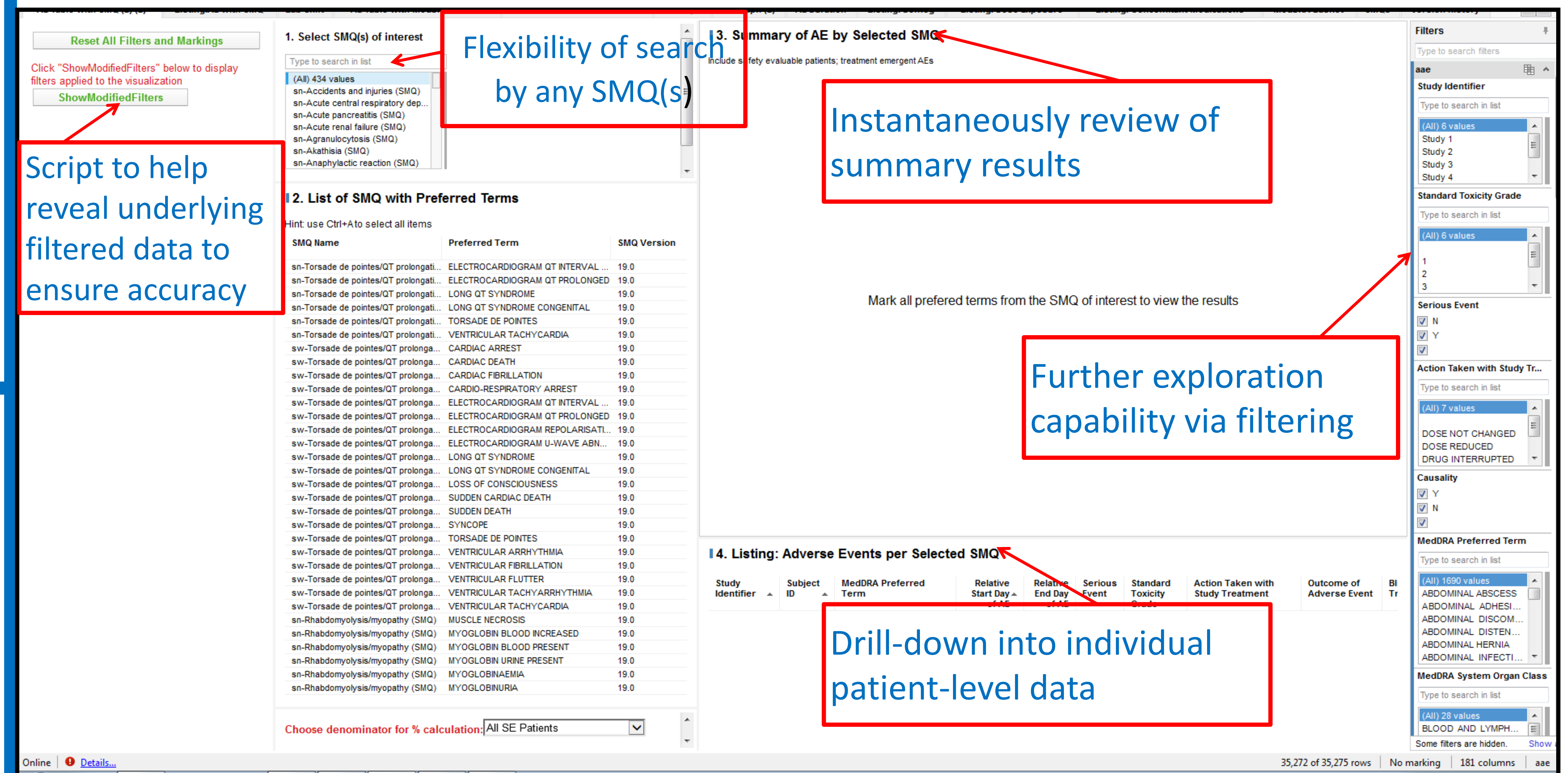
Example Use Case

We leveraged the SMQ exploration tool to support a drug safety report for Acute Kidney Injury (AKI) based on an integrated summary safety (ISS) database. Below shows summary of patients with AKI Relevant serious AEs.



Note the results were generated by simply searching for the “Acute Renal Failure (wide SMQ)”. Subset for serious events was applied by setting “Serious Events”=“Y” in the right filter panel. Additional subgroup analysis can be easily obtained based on any filter(s) as defined on the filter panel.

Dynamic SMQ Search in Spotfire



Benefit Highlights

- **Reproducible signal detection** with industry standard baskets of terms
- Agility with **self-service exploration**
- Effectiveness with **quick data insights**
- Efficiency gain with **time and resource saving**

Further Exploration

While our safety scientists are pleased with the flexibility of dynamic SMQ search tool, we are continuing to explore new capabilities for safety signal detection such as

- Multiaxiality issue (MedDRA dictionary for secondary paths)
- Customized search algorithm (e.g. modified SMQ or AE group terms)
- How to streamline the work flow to support from real-time ongoing safety surveillance to decision-making (i.e., compliance considerations).