

Mini-Sentinel Common Data Model

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on behalf of the Mini-Sentinel Data Core

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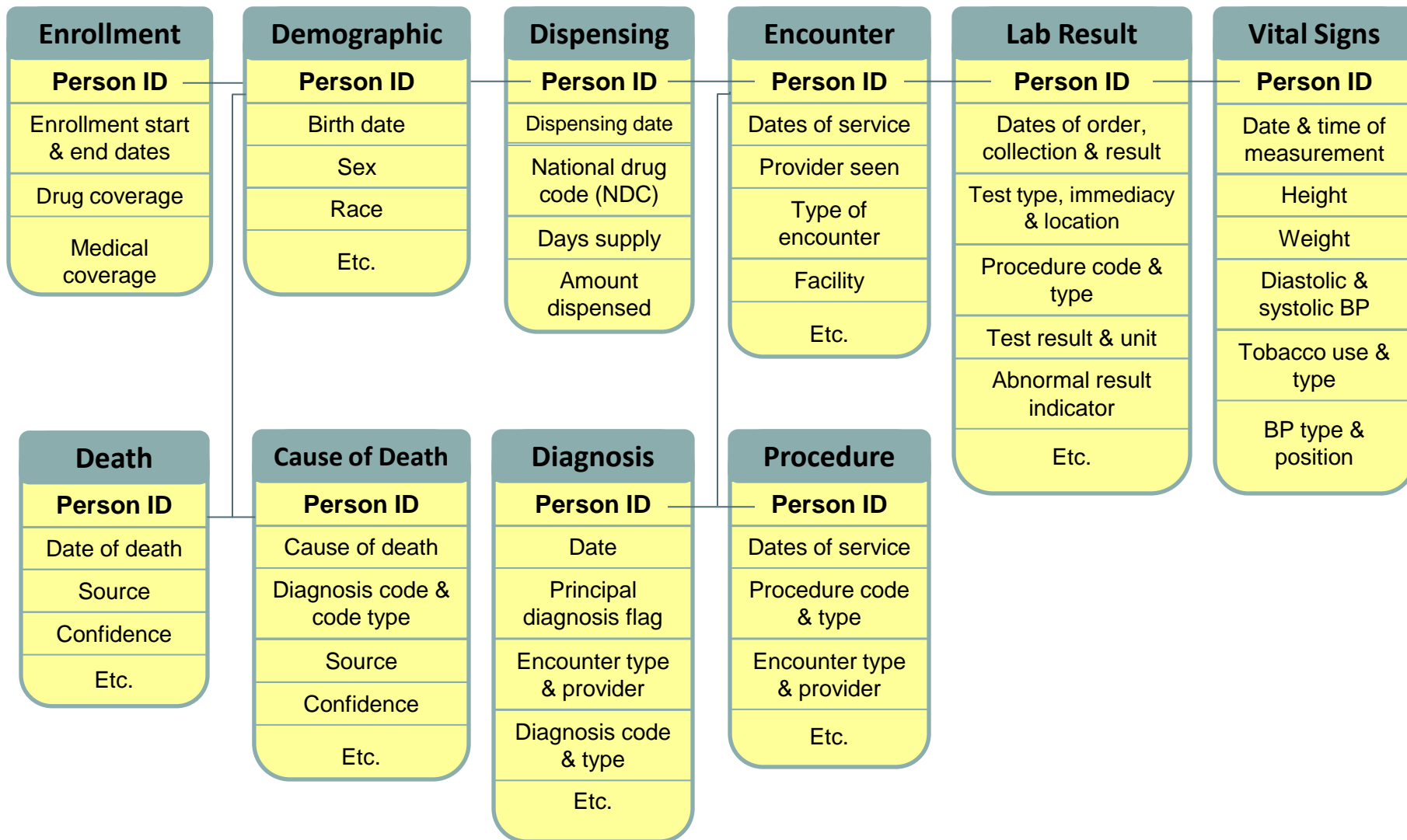
Guiding principles (selected)

- ❑ Accommodates all requirements of Mini-Sentinel and can evolve to meet expanded objectives
- ❑ Able to incorporate new data types and data elements as needs change
- ❑ Leverages existing and evolving data standards
 - Use existing native coding systems; minimize ontology mapping
- ❑ Captures values found in source data
 - With few exceptions, calculated variables are not included

Guiding principles (selected)

- ❑ Transparent, intuitive, well documented design that is easily understood by analysts, investigators, and investigators
- ❑ Local implementation may include “site-specific” variables

Mini-Sentinel's Common Data Model



Ready to use tools for common data model

Home
About Us
Assessments
Methods
Data
Communications
Related Links

Data Activities

- Distributed Database & Common Data Model**
- Distributed Query Tool & Summary Tables**
- Modular Programs**
- Toolkit Library**
- Complementary Data Sources**

Home > Data Activities

Data Activities

Mini-Sentinel uses a distributed data approach in which Data Partners maintain physical and operational control over electronic data in their existing environments. The Mini-Sentinel Common Data Model standardizes administrative and clinical information across Data Partners. Data Partners execute, within their own institutions' firewalls, standardized computer programs (e.g., modular programs) provided by the Operations Center or project workgroups. Data Partners then share the output of these programs with the Operations Center and project workgroups, typically in aggregated form.

A key benefit of the distributed approach is that it minimizes the need to share identifiable patient information. Additionally, each health care data system has unique characteristics, and use of a distributed system better enables the Data Partner's involvement in running analyses to ensure an informed approach to interpreting results.

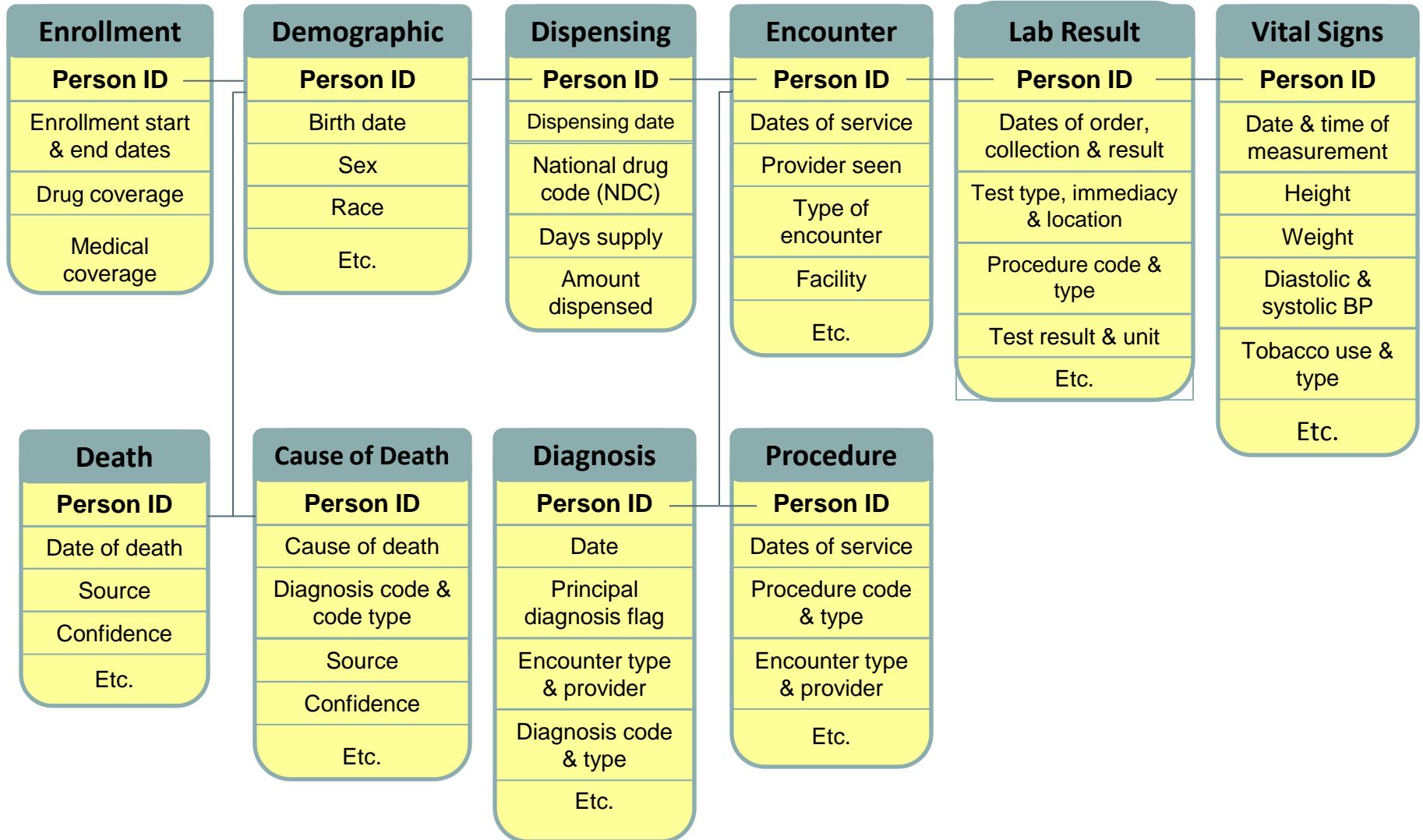
Mini-Sentinel data activities fall into the following general categories. Additional information can be found by clicking on the link to each section.

- [Distributed Database and Common Data Model](#)
- [Distributed Query Tool & Summary Tables](#)
- [Modular Programs](#)
- [Toolkit Library](#)
- [Complementary Data Sources](#)

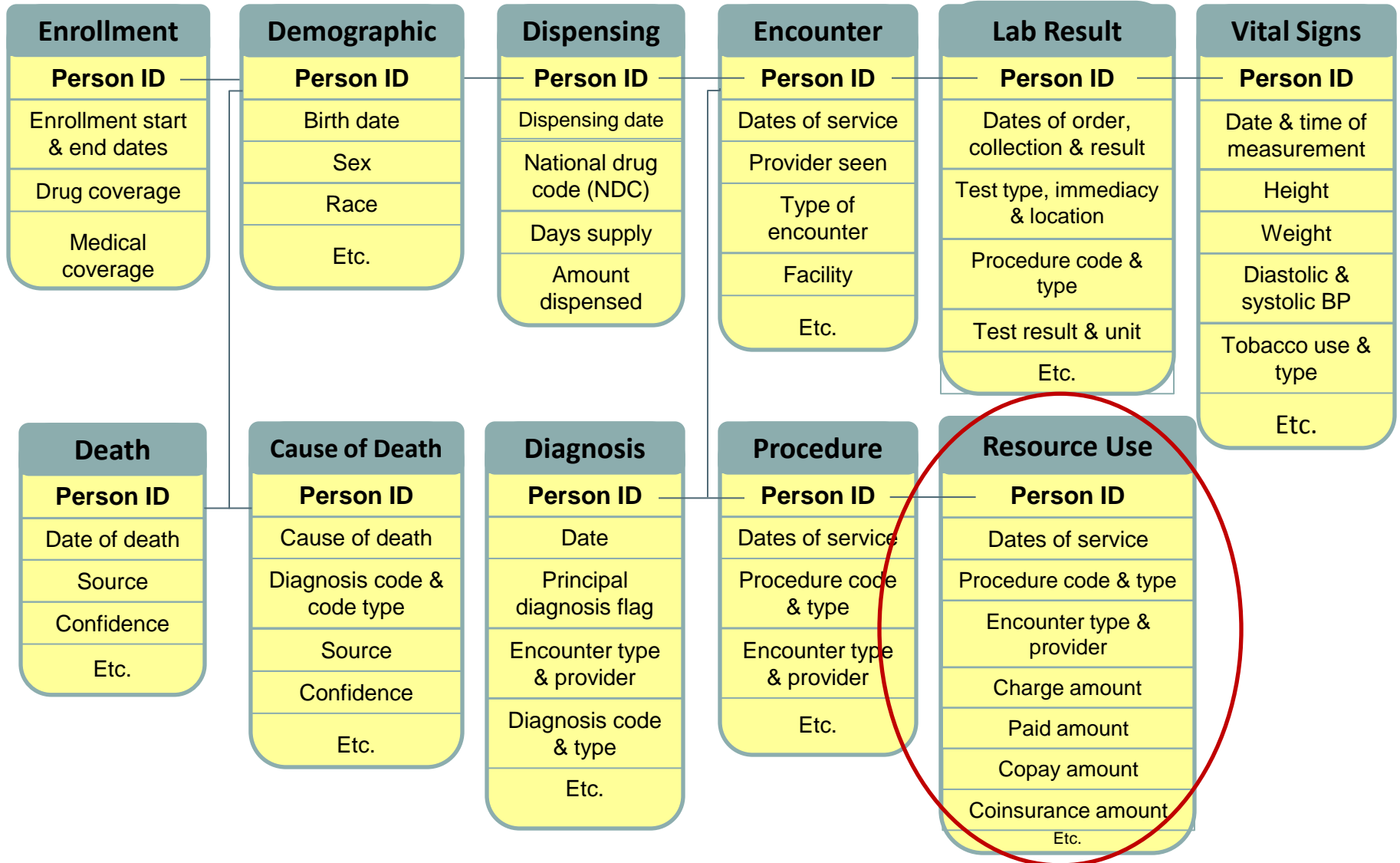
Beyond safety surveillance

- ❑ Reliance on source data allows for translation into other data models
- ❑ Add data elements, tables to address specific needs
 - Resource utilization
 - Performance measurement
 - Comparative effectiveness

Enhanced Common Data Model



Enhanced Common Data Model



Thank you!