

Funding

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Background

- Registries can inform clinical decision making and health care delivery by offering real-world evidence on the effectiveness, safety, and value of products and interventions.
- However, wide variation in outcome measures and definitions, even within narrow clinical areas, presents a significant hurdle in leveraging registry information.
- The Agency for Healthcare Research and Quality (AHRQ) is attempting to address this variation through the Outcome Measures Framework (OMF), a content model for developing harmonized outcome measures in specific disease areas.¹

Objective

Test the robustness of the OMF by mapping outcome measures in two condition areas, valvular heart disease (VHD) and rheumatoid arthritis (RA), to the framework.

Figure 1: RA Mapping Results

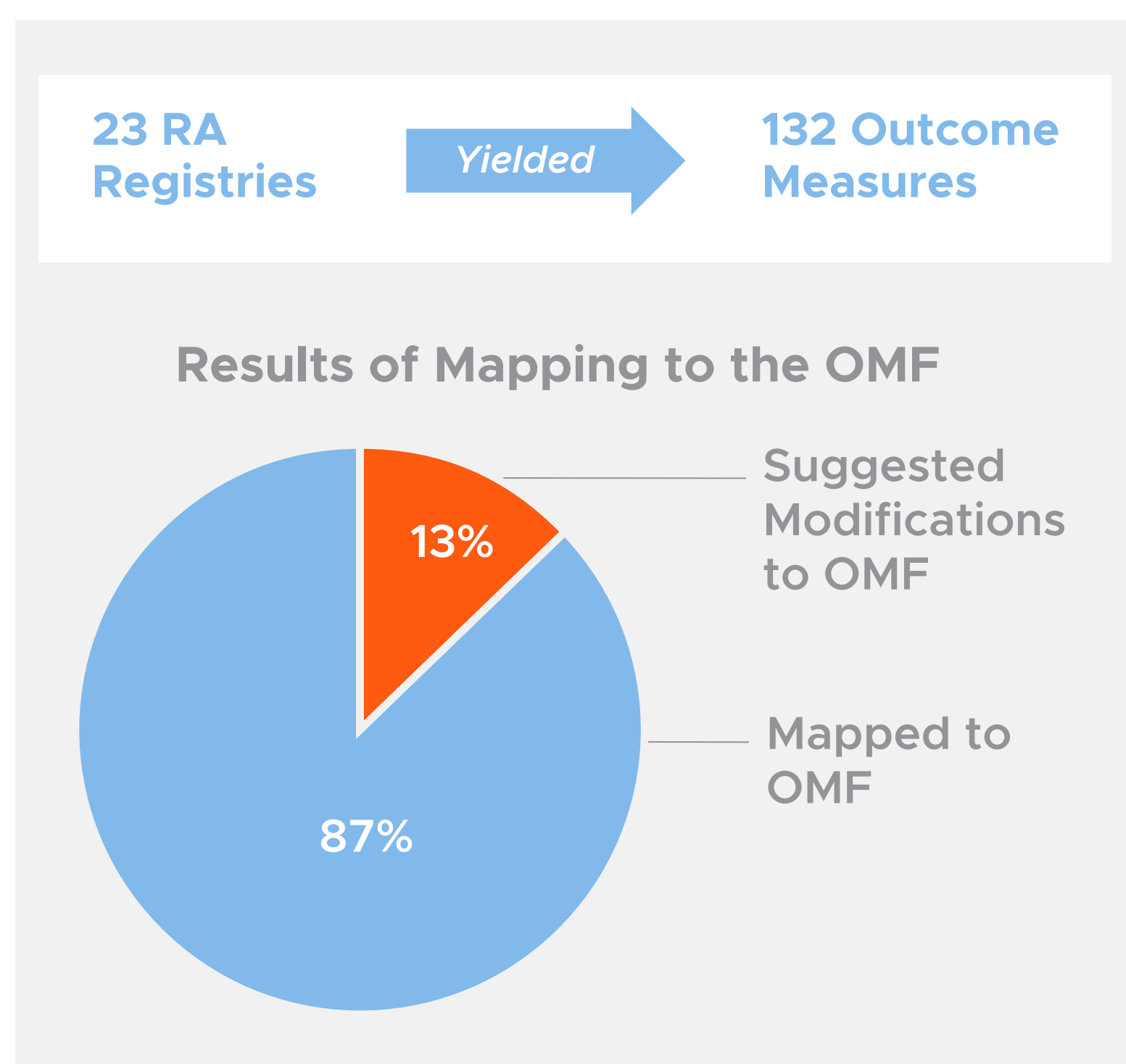
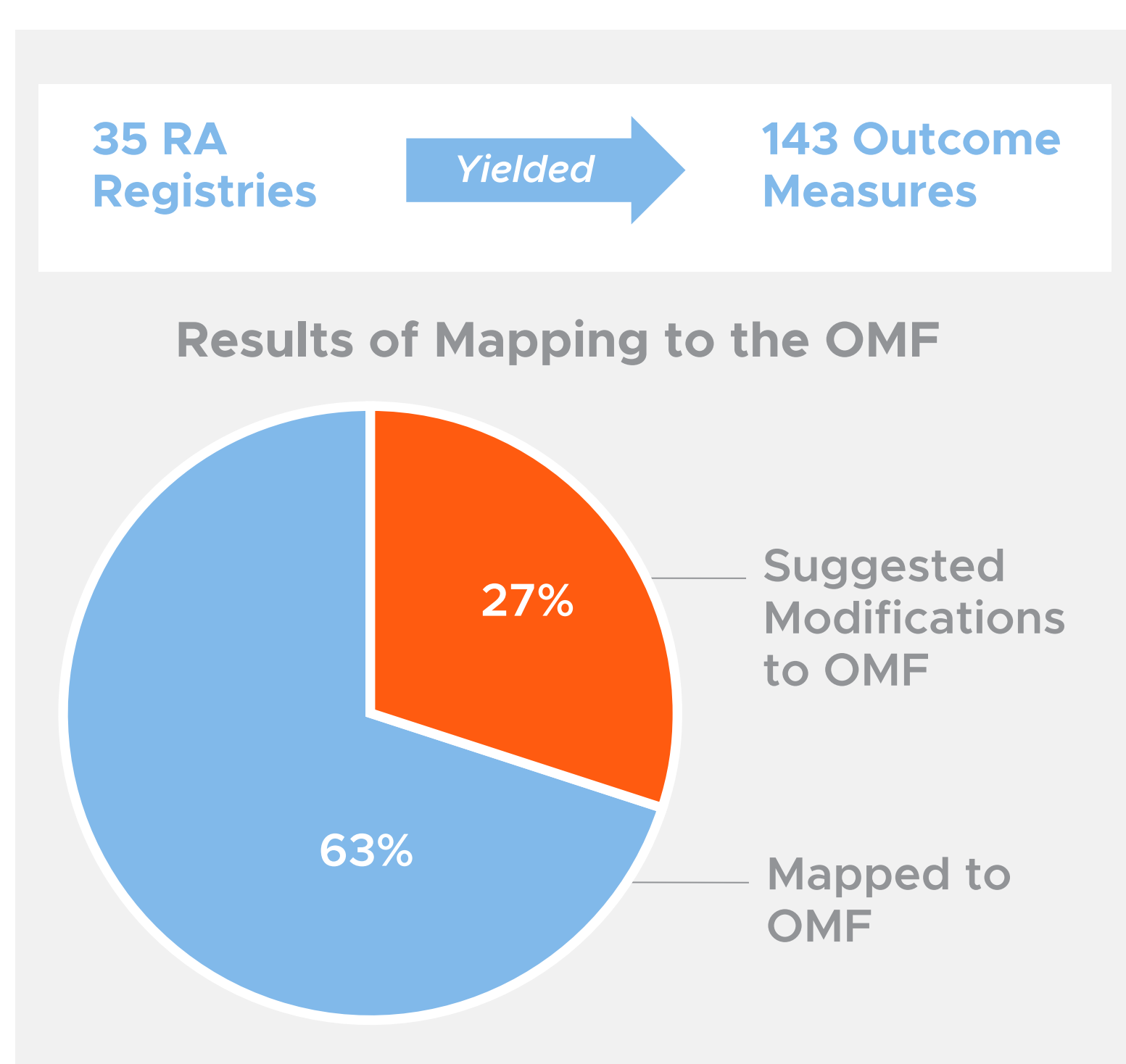


Figure 2: VHD Mapping Results



Results

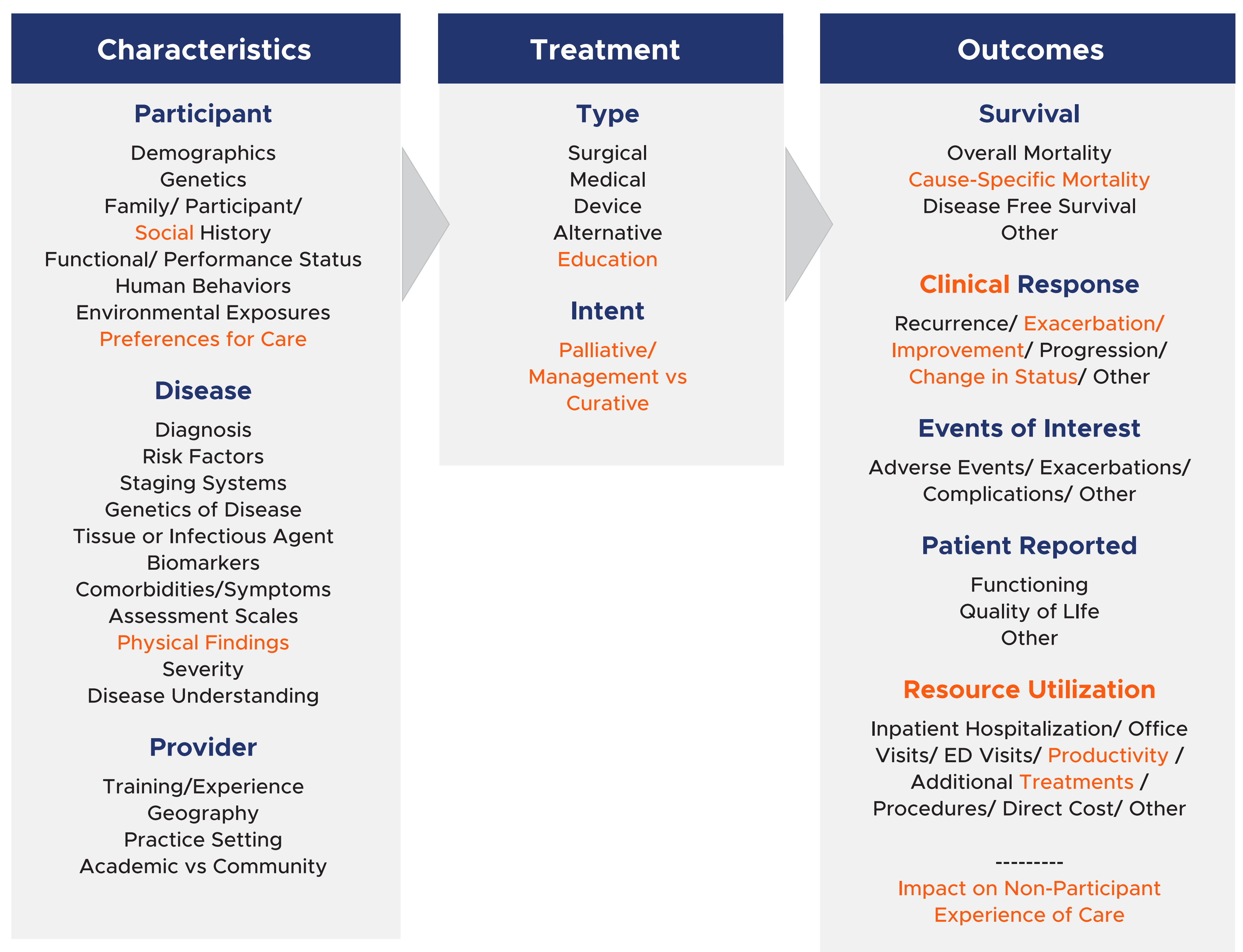
Results of the mapping are shown in **Figure 1** and **2**. Analysis of the measures that did not map directly to the OMF resulted in modifications to the framework, shown in red text in **Figure 3**. In summary:

- ‘Management’ was included as an intent of treatment, along with palliative and curative.
- Case-specific mortality was added a mortality measure example.
- Disease Response category was renamed ‘Clinical Response to cover outcomes for non-disease conditions or trauma.
- Exacerbation and improvement were added to the Recurrence category as examples that demonstrate the range of outcomes that might be included under response.
- Complications was added in the Events of Interest category.

Study Design

- Manual abstracts of outcome measures for VHD and RA from patient registries listed on ClinicalTrials.gov as of June 23, 2015.
- Supplementary internet searches and stakeholder input from professional societies and key opinion leaders used to identify additional relevant registries.
- Two reviewers, one trained in epidemiological research methods and one clinician, independently conducted a manual review of the measures and compared results.

Figure 3. Modified Outcome Measures Framework



Conclusions

The OMF performed well when tested against different condition areas, but the analysis highlighted the need for minor modifications. This study demonstrated the robustness of the OMF for classifying a diverse group of outcome measures. The OMF offers a tool for harmonizing outcomes measures across studies, which in turn improves the utility of registry data in supporting quality improvement and value-based care across a dynamic healthcare system.

References

¹Gliklich RE et al. (2014). A framework for creating standardized outcome measures for patient registries. *J. Comp. Eff. Res.* 3(5), 473–480.

Acknowledgments

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