

Background and Objectives

- The relevance of effective stakeholder engagement to the integrity of RWD-based research has been recognized, with several frameworks published by PCORI, ISPOR/ISPE and others.
- Most of these guidance statements focus on the role of the patient stakeholder, yet clinicians play an especially important role in the generation and interpretation of RWD, given their proximity to the point-of-care where the data originates and role in understanding fitness-for-purpose.
- We therefore sought to develop and apply a conceptual framework for the integration of clinician stakeholder feedback into RWD investigations.

Methods

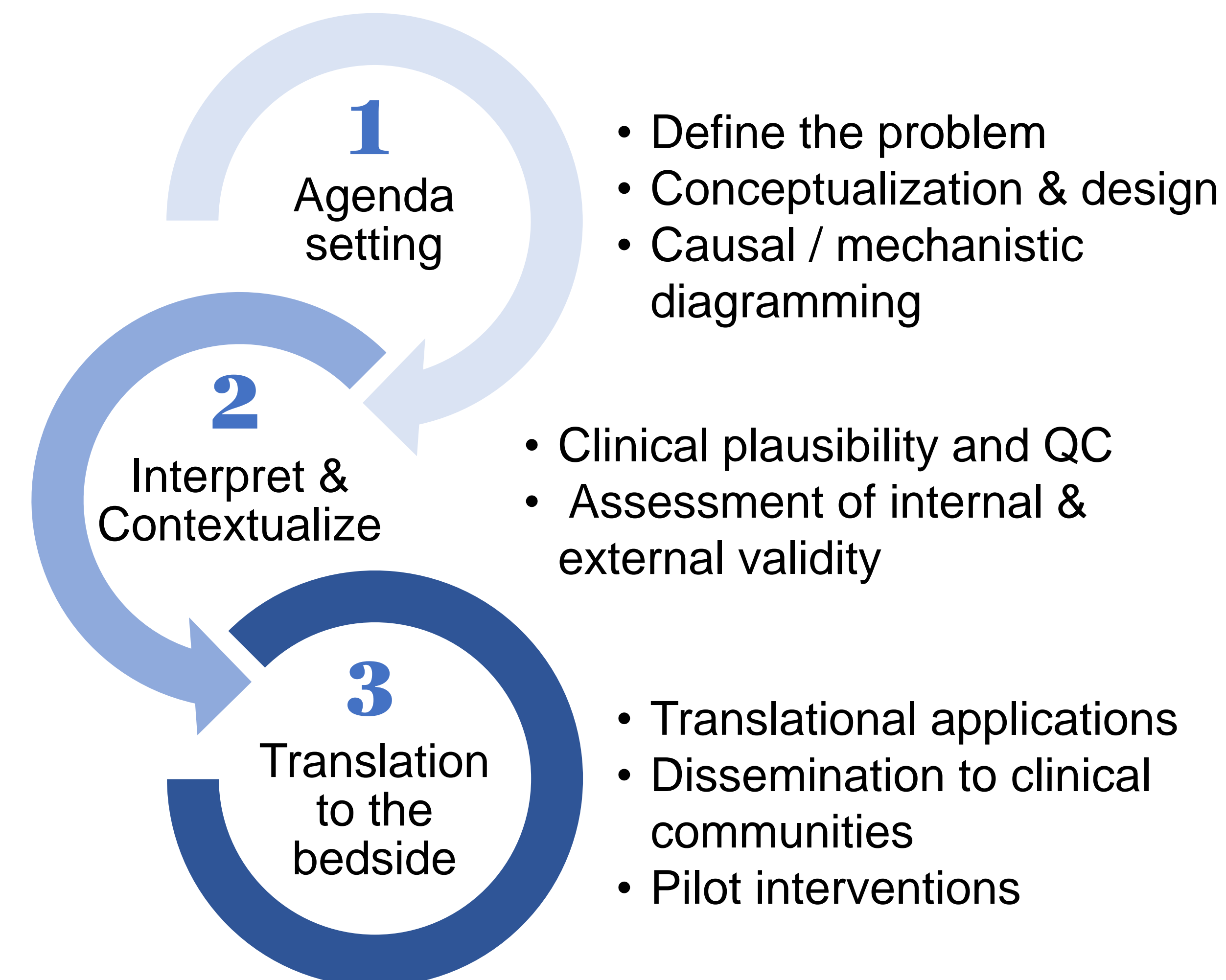
- Literature review identified multiple frameworks and best practices for stakeholder engagement, with an emphasis on patient perspectives.
- The applicability of these to the engagement of physicians in RWD-based studies were discussed with subject-matter experts.
- Leveraging these resources, we developed a framework for systematically integrating clinical stakeholder feedback into RWD-based research and applied it to the design of three RWD studies.
- Engagement methods for clinicians included: focus groups, 1:1 interviews and embedding in real-world research teams

Results

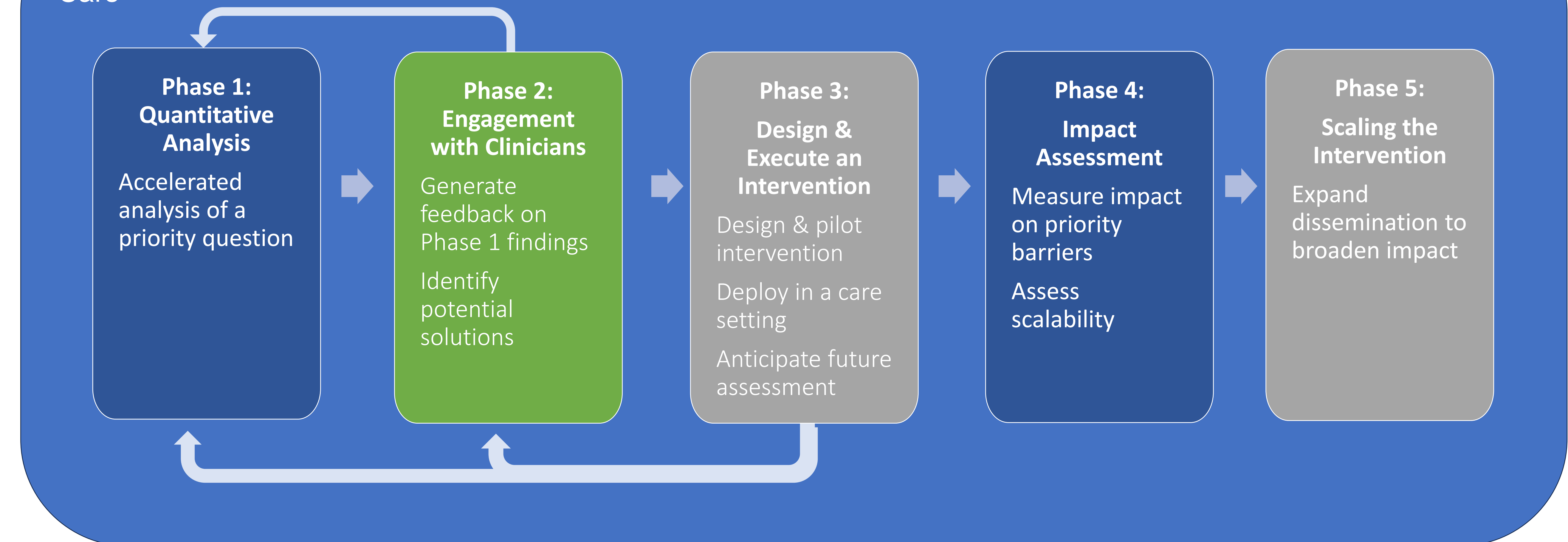
Existing Stakeholder Engagement Frameworks for RWD:

- 7Ps and 6 Stage Framework (Concannon, 2012)
- Patient Centered Outcomes Research Institute (PCORI) Engagement Framework
- Duke Margolis Real World Evidence Collaborative White Papers
- ISPOR/ISPE Task Force (Berger, 2017)
- Multi Stakeholder Engagement (MuSE) Consortium (2019-2020)
- Joint ISPOR-ISPE Special Task Force on Real-World Evidence (Oehrlein, 2023)

Figure 1. Three Opportunities for Engaging Clinician Stakeholders in RWD Studies



Case Study 1. Model for Clinician Stakeholder Engagement to Catalyze Interventions at Scale to Transform Cancer Care






Case Study 2. Clinician Insights are Critical for Model Validity and Clinical Implementation

Developed a prediction model with 8 variables to predict time to progression for patients with HR+/HER2- metastatic breast cancer

A focus group of 8 oncologists engaged to provide feedback on model performance and clinical utility

Focus group was executed with a structured discussion guide, and co-facilitated by an oncologist and epidemiologist

Emergent themes:

-  Oncologists reported uncertainty in decision making → Prioritized investment in boosting model performance
-  Primacy of biomarker data for treatment decisions → New model developed with enriched biomarker data
-  Keeping pace with rapidly evolving treatment landscape → New model designed with real-time updating

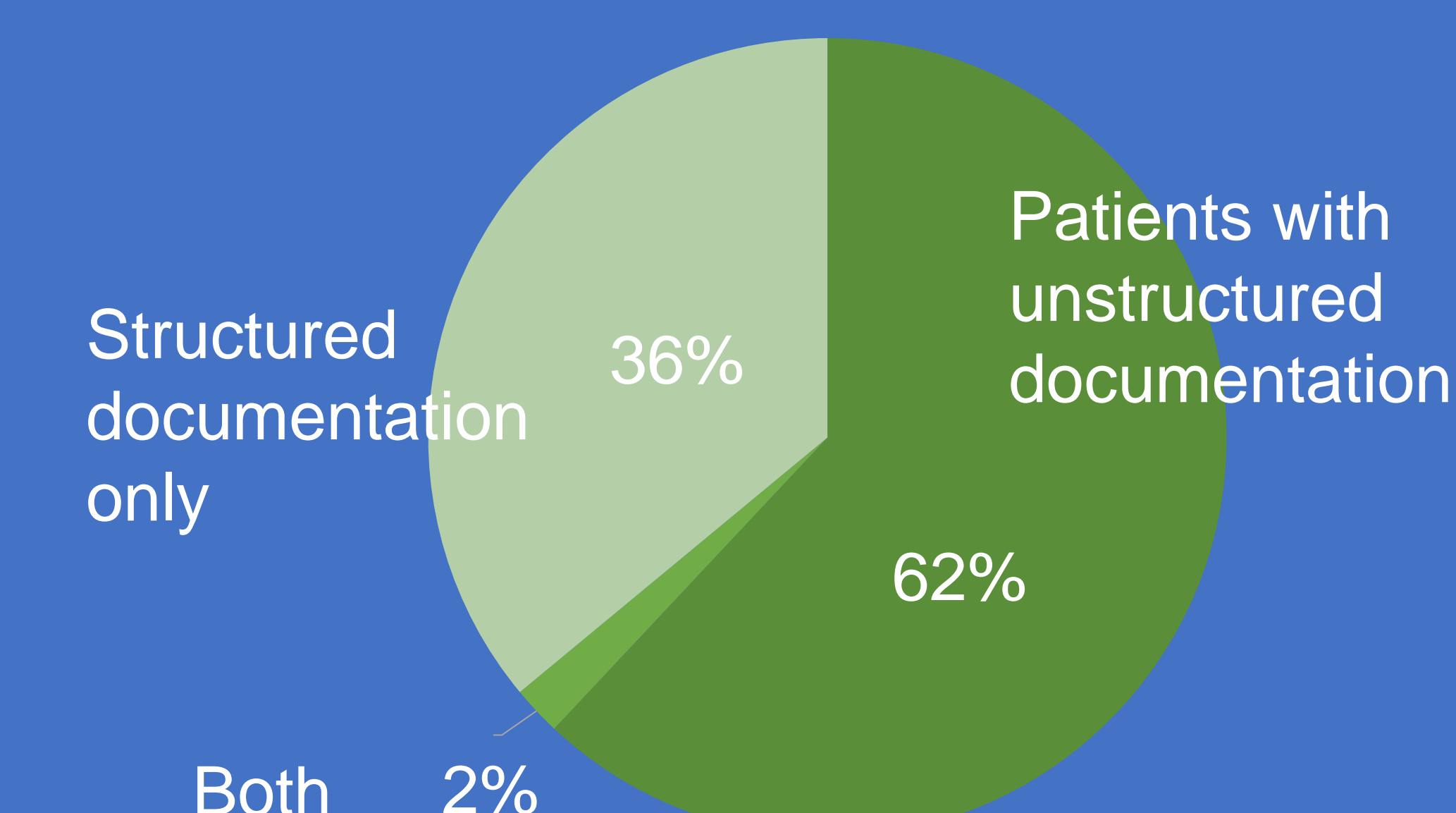
Case Study 3. Clinician Input Critical to RWD Assessment of Biomarker Testing Trends in Lung Cancer

Medical oncologists engaged in concept development, protocol development and guided chart abstraction exercises

Oncologist identified unreliability of structured data assessments

Estimate of testing rose from ~60% to ~90% after chart abstraction pilot

Clinician stakeholder involvement allowed conservation of additional chart efforts; de-prioritization of clinician education campaign



Conclusions

- We developed a novel framework to improve the translational potential of RWD studies through engagement of clinician stakeholders.
- Clinicians should be engaged as early as possible in the design of RWD studies, during agenda setting and study conceptualization.
- Clinician stakeholder engagement significantly improved the efficiency of RWD-based research studies – including conserving chart abstraction efforts and aligning research products more closely to a potential clinical application.
- Integration of clinician perspectives has important implications for accelerating the impact of RWD-based research, including improvements in care quality, shared decision making and promoting clinical validity of novel methods such as generative artificial intelligence.