Completion rate and time analysis of electronic quality of life measures

Authors   Reina Davis-Aoki, M.S., Ph.D., Clinical Science Associate, eCOA Clinical Science and Consulting
Kelly Dumais, Ph.D., Director, eCOA Clinical Science and Consulting

Introduction

Quality of life (QoL) measures are critical to assess patients' health in clinical trials. There has been increased regulatory attention on designing more patient-centric clinical trials[1], with emphasis on reducing the burden on patients to participate. One way to reduce burden is providing more convenient methods for collecting QoL measures, such as the use of electronic patient-reported outcomes (ePROs). We aimed to understand how electronically administered QoL measures are utilized in studies, including their completion time and rate using metadata.

Methods

Participants completed assessments electronically on Clario Tablet devices at clinical trial sites. Operational data were extracted and analyzed for four commonly used patient-reported QoL measures: EQ-5D-5L (five levels of severity), EQ-5D-3L (three levels of severity), SF-36v2 Standard and SF-36v2 Acute.

Results

The sample included 116 studies across different therapeutic areas and phases, with 120,565 instances of completion status analyzed for the four QoL measures.
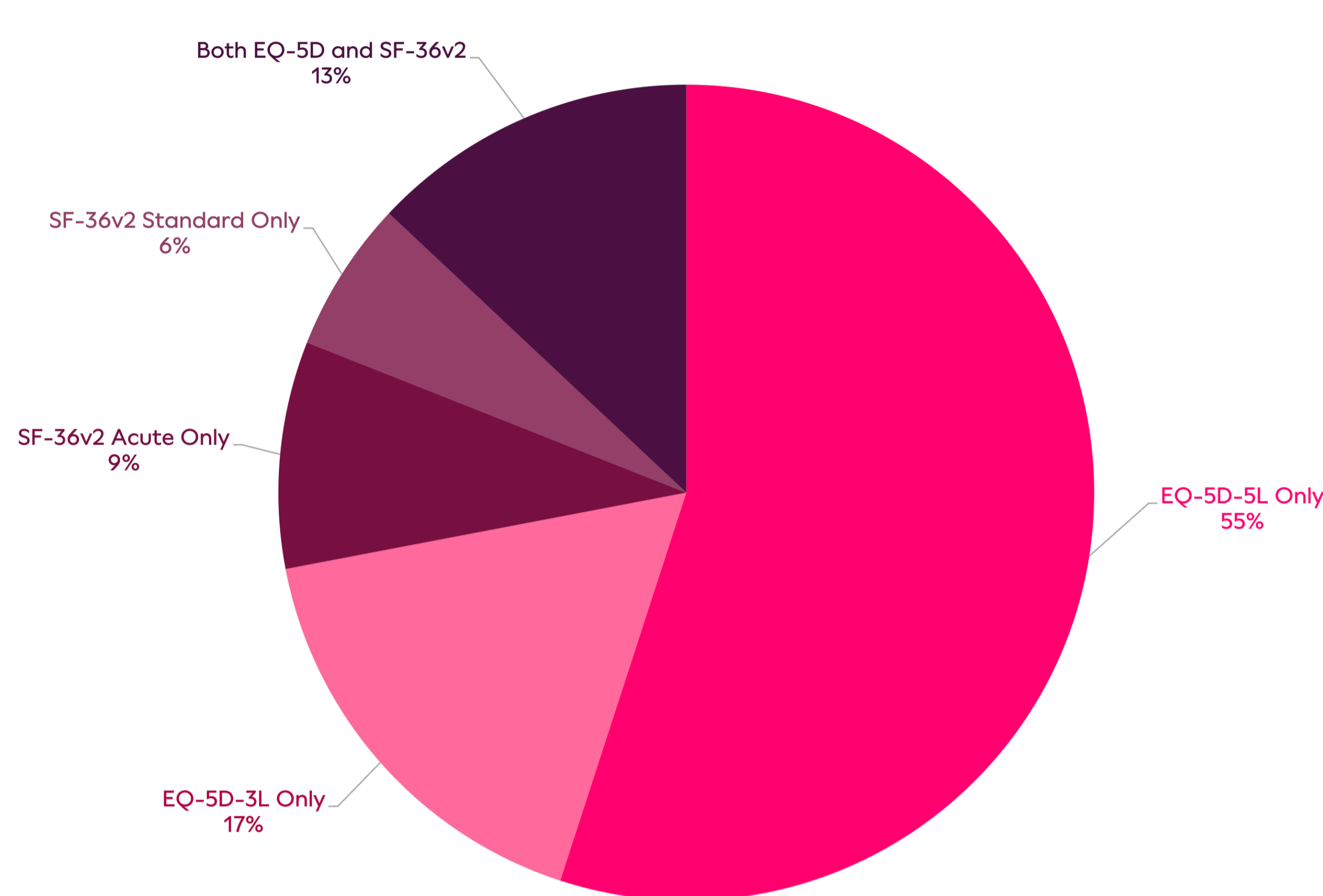

Figure 1: Percentage of studies using each QoL measure
Independently, EQ-5D-5L was the most frequently used QoL measure (in 64 studies), followed by EQ-5D-3L (in 20 studies), then SF-36v2 Acute (in 10 studies), and finally SF-36v2 Acute (in seven studies). Some studies used different combinations of EQ-5D and SF-36v2 versions (EQ-5D-5L + SF-36v2 Standard in seven studies, EQ-5D-3L + SF-36v2 Standard in six studies, and EQ-5D-5L + SF-36v2 Acute in two studies).
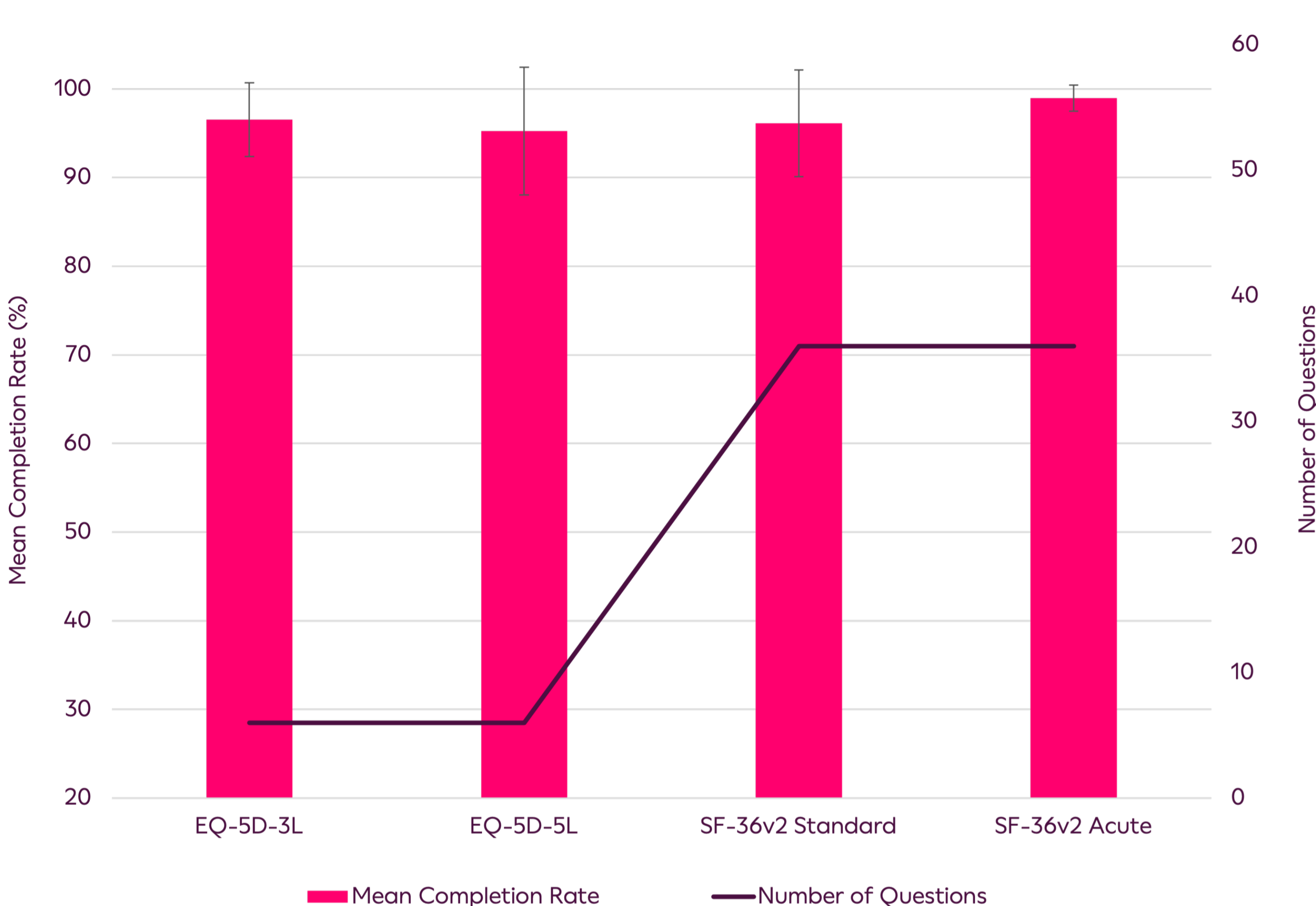

Figure 2. QoL measures used across therapeutic areas
The QoL measures used in the studies varied according to the therapeutic area. For instance, EQ-5D-5L was most frequently used in Oncology and Central Nervous System studies, whereas EQ-5D-3L was predominantly used in Dermatology studies. Both SF-36 assessments were most commonly used in Immunology studies.

Figure 3. Mean Completion Rates and Number of Questions
The mean completion rates were 96.5% (EQ-5D-3L), 95.2% (EQ-5D-5L), 96.1% (SF-36v2 Standard) and 99.0% (SF-36v2 Acute). The number of questions in assessments had no correlation with the completion rates.
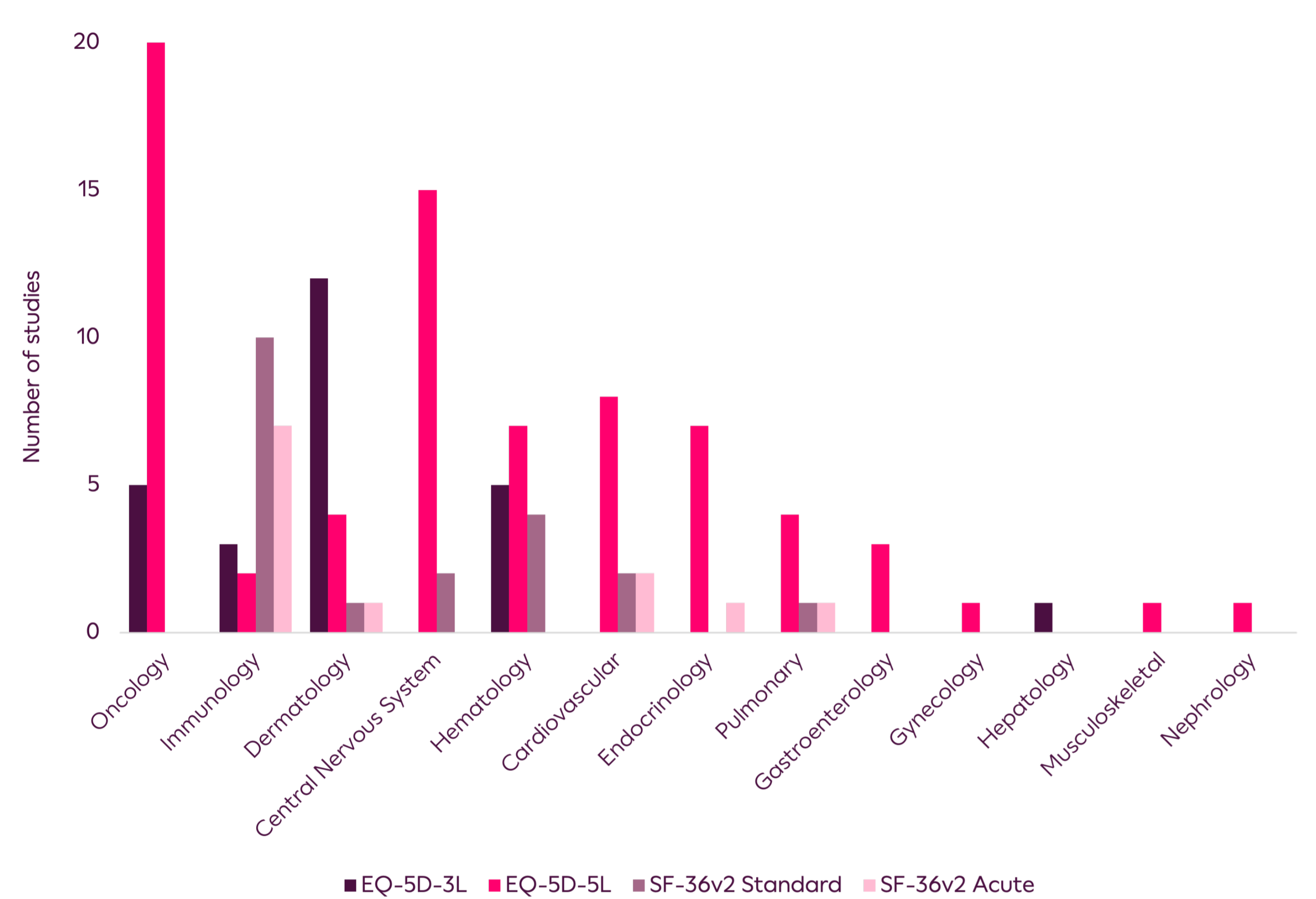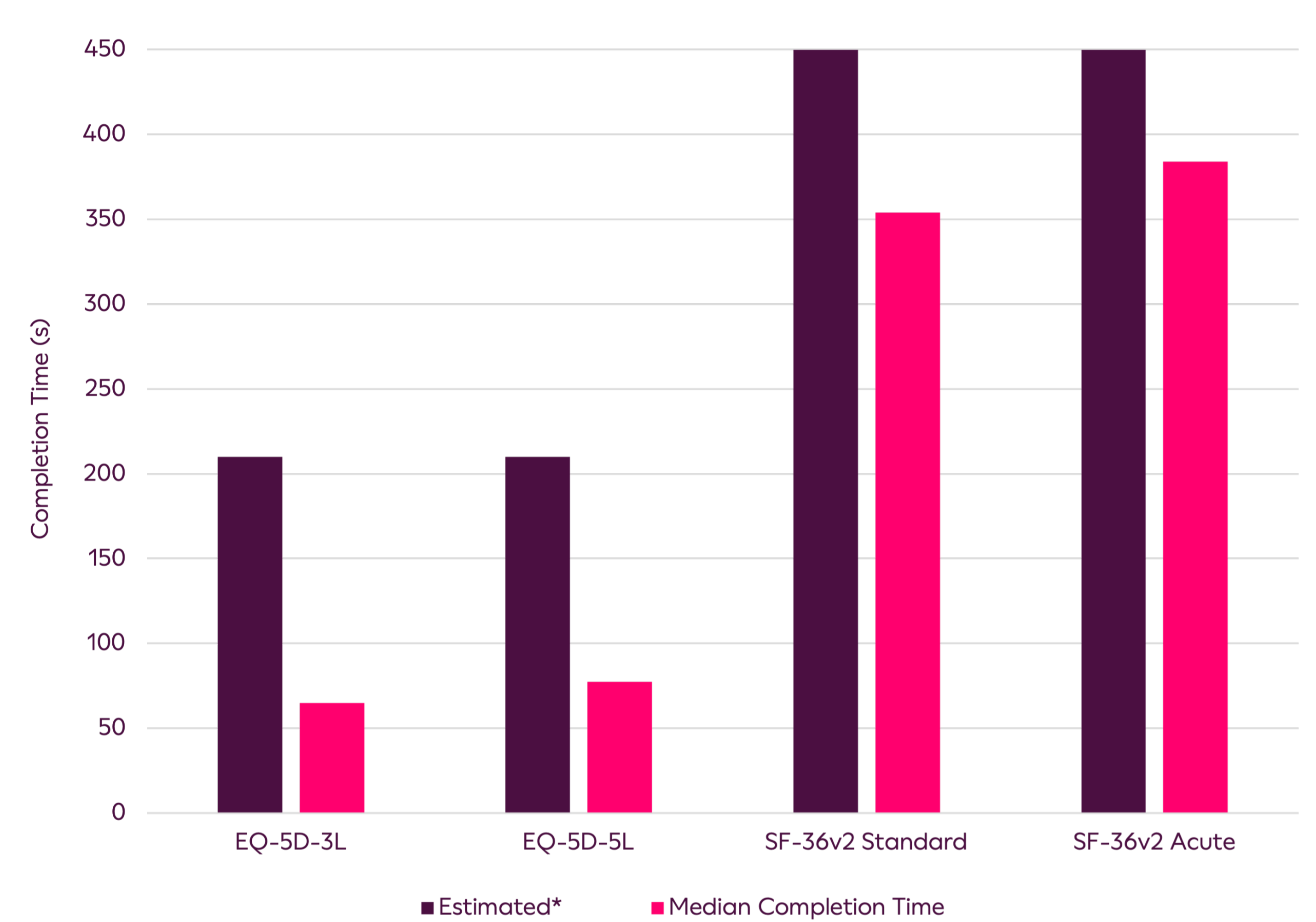

Figure 4. Median vs Estimated Completion Time
The study specific median time for form completion was 65s for EQ-5D-3L (range 17-114s), 80s for EQ-5D-5L (range 43-157s), 354s for SF-36v2 Standard (range 129-455s) and 384s for SF-36v2 Acute (range 256-7840s). All assessments took less time to complete than the estimates. *The estimated completion times for SF-36v2 and EQ-5D were derived by taking the mid-points of the range provided by Mapi Research Trust[2] and Jin, X et al.,[3] respectively.

Conclusions

- Among the four QoL measures, EQ-5D-5L was the most frequently used. Different versions of EQ-5D and SF-36v2 were employed in various combinations, with the choice of QoL measure varying for each therapeutic area.

- Completion compliance was high for all tablet QoL measures regardless of completion time or number of questions. This suggests that longer QoL measures may not negatively impact compliance at site, and that electronic measures have benefits of yielding high compliance and enhanced data quality.

The analysis of instances where the assessments were completed at home was not feasible due to the limited sample size. Additional analysis of home-based assessments will determine any potential impact of location on compliance.

References
1. Patient-Focused Drug Development: Selecting, Developing, or Modifying Fit-for-Purpose Clinical Outcome Assessments, Draft Guidance, FDA, June 2022
2. SF-36 Health Survey (SF-36® / SF-36v2®) ePROVIDE™ by Mapi Research Trust
3. Jin, X., Al Sayah, F., Ohinmaa, A., Marshall, D. A., Smith, C., & Johnson, J. A. (2019). The EQ-5D-5L Is Superior to the -3L Version in Measuring Health-related Quality of Life in Patients Awaiting THA or TKA. Clinical orthopaedics and related research, 477⑦, 1632–1644.