

# Appendix 9



## Hierarchical list of references/sources used to define the SISAQOL-IMI glossary terms

### References/sources

1. European Medicines Agency (EMA). International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidance documents (ICH) Topic E9: Statistical principles for clinical trials. CPMP/ICH/363/96. 1998 Sep.

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European Medicines Agency (EMA). ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials. Step 5. EMA/CHMP/ICH/436221/2017. 2020 Feb 17 [cited 25/06/2024]. Available from: <https://www.ema.europa.eu/en/ich-e9-statistical-principles-clinical-trials-scientific-guideline>

2. U.S. Food and Drug Administration (FDA). Patient-Focused Drug Development Glossary. Content current as of: 2018 Jun 08 [cited 25/06/2024]. Available from: <https://www.fda.gov/drugs/development-approval-process-drugs/patient-focused-drug-development-glossary>
3. Dictionary of Quality of Life and Health Outcomes Measurement. Nancy E. Mayo (Ed.). ISOQOL. 2015 First edition. (See <https://www.isoqol.org/> for more information)  
Approval for use of terms and definitions in the SISAQOL-IMI glossary was granted by ISOQOL in June 2024.
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5. National Cancer Institute. NCI Dictionary of Cancer Terms [Internet]. Available from: <https://www.cancer.gov/publications/dictionaries/cancer-terms>
6. Calvert M, Kyte D, Mercieca-Bebber R, et al. Guidelines for inclusion of patient-reported outcomes in clinical trial protocols: the SPIRIT-PRO extension. *JAMA*. 2018;319(5):483–494. doi: 10.1001/jama.2017.21903
7. U.S. Food and Drug Administration (FDA). Oncology Center of Excellence. Patient-friendly language for cancer clinical trials [Internet]. Content current as of: 2021 Feb 16 [cited 25/06/2024]. Available from: <https://www.fda.gov/about-fda/oncology-center-excellence/patient-friendly-language-cancer-clinical-trials>