

■ ZUR SACHE

The Challenge of Data Requirements for Pricing and Reimbursement Procedures

Demonstrating a Drug's Value – How to Deal with Missing Data?

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References

EUnetHTA, EMA (2013) Joint press release: European Medicines Agency and EUnetHTA agree joint work plan (EMA/669498/2013 – 19 November 2013). URL: www.eunetha.eu following the menu "NEWS > (19 November 2013)" (Last request: 14.08.2015)

IQWiG – Allgemeine Methoden (version 4.2, dated 22 April 2015).

Lebioda A, Gasche D, Dippel FW, Theobald K, Plantör S. Relevance of indirect comparisons in the German early benefit assessment and in comparison to HTA processes in England, France and Scotland. Health Economics Review 2014.

Schneeweiss S, Gagne JJ, Glynn RJ, Ruhl M, Rassen JA. Assessing the comparative effectiveness of newly marketed medications: methodological challenges and implications for drug development. Clinical pharmacology & Therapeutics 2011; 90(6):777-790.

EUnetHTA guideline "comparators & comparisons: direct and indirect comparison. URL: www.eunetha.eu following the menu "OUTPUT > EUNETHTA GUIDELINES – READ MORE > 7. Direct and indirect comparison" (Last request: 14.08.2015)

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