On the first of June of 2015, it was published legislation that determines the creation of the National Institute for Health and Care Excellence (NICE) with the purpose to obtain an improvement of health status, in line with other European systems. Portugal was one of the first countries to officially adopt methodological guidelines for economic drug evaluation studies. When it was first published in 1990, it was established that these guidelines were to be revised once the scientific knowledge and the international standards advised it. However, and after 16 years of its publication, it was never reviewed. Currently this work is being done, as one of the objectives of SINATSA was summarized in 3 steps: First: A systematic literature review (SLR) and a subsequent assessment of the feasibility of a network meta-analysis (NMA) based on the published evidence for existing treatments of interest is conducted. The key markets of interest and their HTA authorities are taken into account in this phase to define the SLR criteria. Second: Based on the calculations within a Bayesian framework, the sensitivity of the results of a future NMA, if this new treatment is included, can be explored. A distribution of the new treatment’s effects under the existing NMA is assumed as prior distributions for relevant parameters, and if/ or the target product profile. The SLR and the NMA results can inform the phase III study design, e.g. regarding the appropriate comparators, outcomes, population and duration. These results can also inform an early market access strategy based on the relative efficacy of the new treatment compared to existing treatments. Third: Once the results of the phase III trial(s) are available, a well-designed SLR and NMA can be easily updated and used for the HTA submissions, with the appropriate adaptations per country. The proposed process could aid in earlier understanding of the relative efficacy of a new treatment to the treatments and outcomes of interest, and in taking early informed decisions about the clinical development and market access strategy. An illustrative example will be provided assuming a new COPD drug and its relative efficacy by means of trough FEV1 and %SGRQ responders.

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A FRAMEWORK FOR PRIORITIZING RESEARCH INVESTMENTS IN PRECISION MEDICINE
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PURPOSE: To advance precision medicine (PM) has been limited in practice to date, and yet its promise has attracted research investments. Developing foundational economic approaches for directing proper use of PM and stimulating growth in this field is critical from the perspectives of patients, providers, and payers. To fill this gap, our previously developed Expected Value of Individualized Care (EVIC) framework, we conceptualize new decision-relevant metrics to better understand and forecast the expected value of PM. Several aspects of behavior at the patient, physician, and the payer level are considered that can influence the rate and manner in which PM innovations diffuse throughout the relevant population. We illustrate this framework and the methods used a retrospective evaluation of the use of OncotypeDx genomic test among breast cancer patients. RESULTS: The enriched metrics can help inform many facets of PM decision making, such as evaluating alternative reimbursement levels for PM tests, implementation and education programs for physicians and patients, and decisions around research investments by manufacturers. We replicated prior published results on evaluation of OncotypeDx among breast cancer patients, but also illustrated that these results are based on assumptions that are often not met in practice. Instead, we show how incorporating more practical aspects of behavior around PM could lead to drastically different estimates of value. For OncotypeDx, population returns to a social insurer ranged from $17 Billions to $37 Billions and from $4 Billions to $10 Billions in revenues不同的 estimates of value. For OncotypeDx, population returns to a social insurer

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VALIDATION OF SOCIAL MEDIA ANALYSIS FOR OUTCOMES RESEARCH: IDENTIFICATION OF DRIVERS OF SWITCHES BETWEEN ORAL AND INJECTABLE THERAPIES FOR MULTIPLE SCLEROSIS
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OBJECTIVES: Social media is increasingly used by patient seeking information about drugs and has been analysed to understand attitudes, behaviours and perceptions. However the applicability of social media analysis to address specific questions in outcomes research is largely untested. We analysed the representativeness of social-media populations and employed social intelligence methodology to study treatment-switching patterns from oral therapies to multiple sclerosis (MS). METHODS: A comprehensive listening and analysis process was developed which blends automated listening with filtering and analysis of social-media data by life-sciences qualified analysts and physicians. The population was patients with MS from the United States. Data sources were Facebook, Twitter, blogs and online forums which were searched for mention of Tecfidera and Gilenya as examples of oral MS treatments. RESULTS: A total of 10,260 extracted data points were pertinent to the objectives and included in the analysis. Women aged 30–49 and diagnosed for ≥ 10 years were more active on social media platforms than other MS patients. The identified population was highly similar to that identified in other studies over the past 5 years. Studies with a single experimental arm compared to usual protocols or completed studies. METHODS: A scoring grid with criteria for scores 1 to 5, in each of the 9 domains of PRECIS-2 ('Eligibility', 'Recruitment', 'Setting', 'Organisation', 'Flexibility: Delivery', 'Flexibility: Adherence', 'Follow-up', 'Primary Outcome' and 'Primary Analysis') was constructed by reviewing the scoring assigned to example trials in the PRECIS-2 publication and by reviewing the subjective guidelines provided by the authors. A structured literature review was conducted in PubMed (search terms “pragmatic[title] AND trial[title]”) to find pragmatic trials from 2010 to 2015 that fulfilled a list of 15 criteria. RESULTS: Of 341 search results, 8 surgical trials and 11 pharmaceutical trials were included. No trials were considered ‘very pragmatic’ (score 5) in all 9 domains. ‘Recruitment’ and ‘Flexibility: Adherence’ were not reported in several studies (3 and 9, respectively). On average, surgical trials and pharmaceutical trials were comparable in the degree of pragmatism (mean score [SD]: 4.2 [1.0] vs 4.1 [1.0]). CONCLUSIONS: Our PRECIS-2 scoring grid provides a tool for objective evaluation of pragmatic trials. The next step should be to validate the scoring grid across more reviewers and to apply the grid to a broader range of pragmatic trials.