

Objectives

Healthcare systems across the globe are currently challenged by ensuring better budgetary control and access to high-cost innovative therapies introduced into the cancer treatment. Risk-sharing agreement (RSA) is a management tool, which link the patient access and payment to the manufacturer according to drug clinical benefit. This study makes a systematic review of the research on RSA and cancer drugs.

Methods

A systematic review has been conducted in Web of Science database up to December 2018. Articles were selected by following strategy of search in titles, abstracts and keywords: 1="risk-sharing" and oncology; 2="risk-sharing" and "cancer drug"; #1 OR #2. The search resulted in a total of 23 articles after evaluation of inclusion criteria of the study. All the papers were classified based on main theme, as detailed in Figure 1

Results

The 23 selected works were taken from 18 different journals, 12 works were published from 2016 and most of studies were conducted in Europe (17 works). RSA application differs across countries and over time. There is not yet a gold standard methodology in relation to the type of RSA to be practiced. Between 2010 and 2015, most articles evaluated RSA models (5 works), many based on real-world data (3 works). Between 2016 and 2018, articles on RSA models (7 works) were also predominant, but with the use of clinical trial data (3 works). There is a trend of greater academic interest in RSA research (See Figure 2).

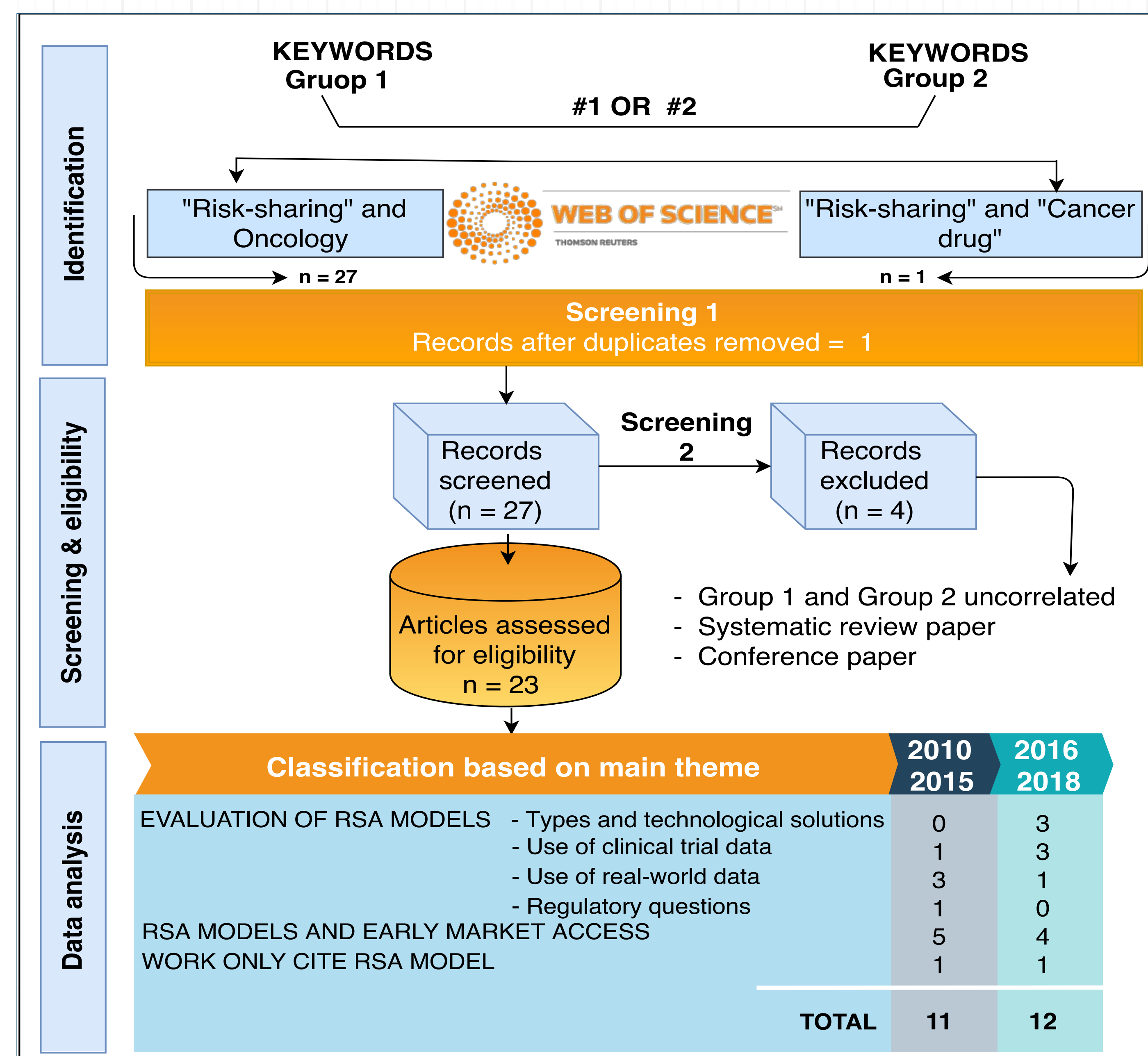


Figure 1: Methodology and results of the systematic review

There are still many limitations to the use of RSA and the results differ across countries and in different analysis for the same country. Financial based agreements are prevailing due to their simplicity compared to performance-based agreements and most studies cite Italian examples of RSA (see Figure 3).

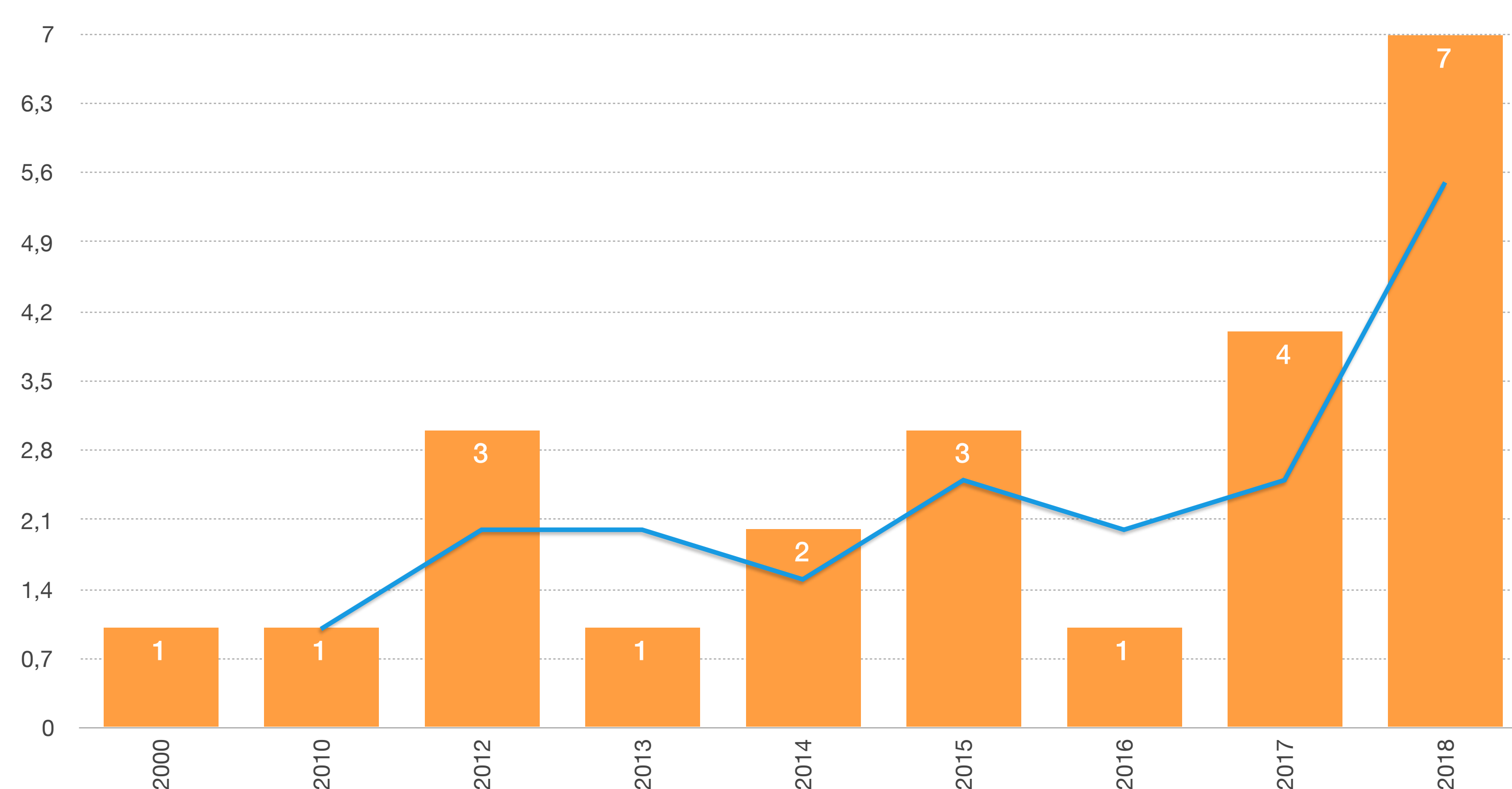


Figure 2: Publications year x Publication number

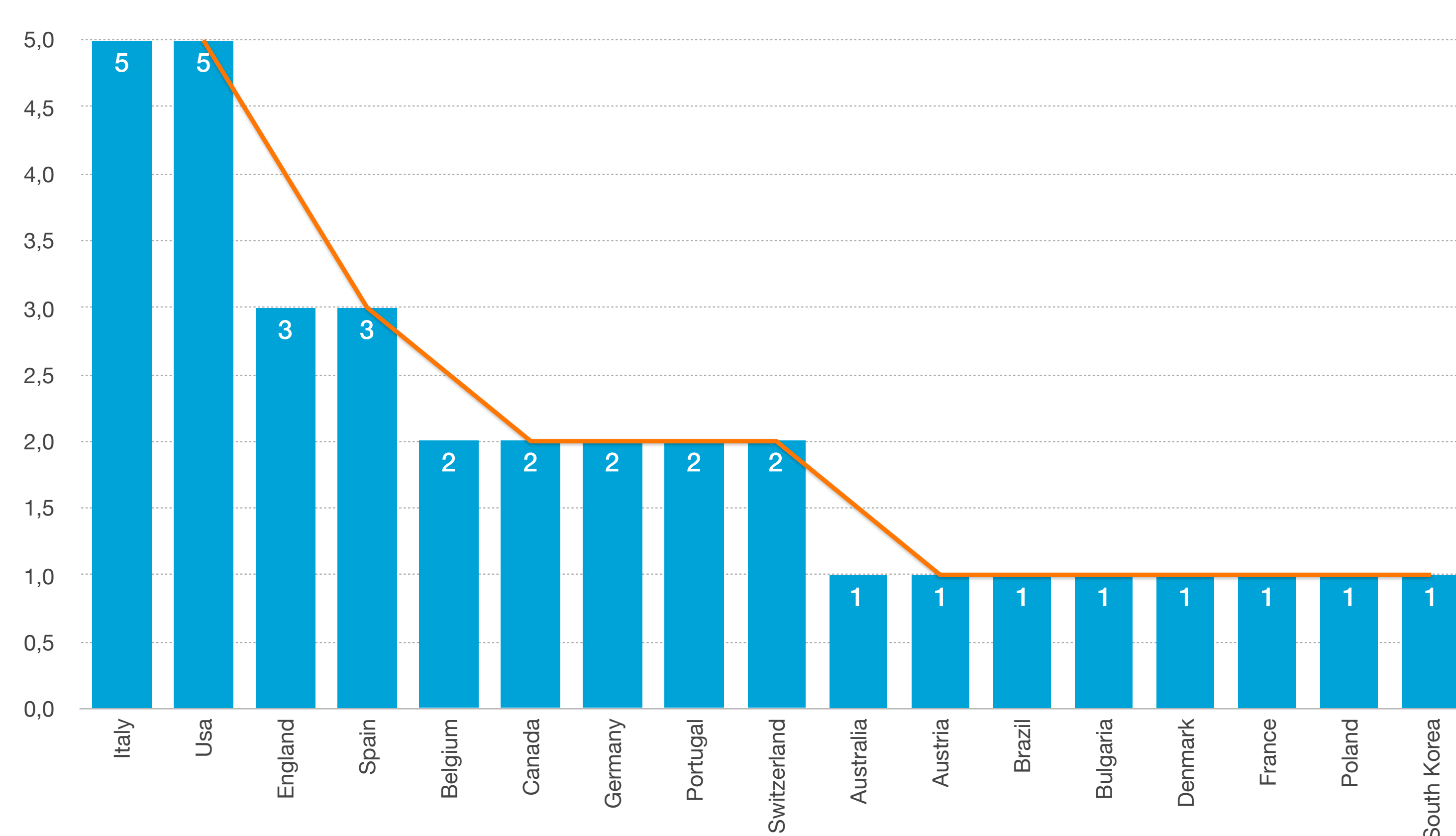


Figure 3: Publications number x countries/Regions

Conclusions

In the literature there has been interest in the potential for RSA, but little information is publicly available, mainly with real-world data. Examples to date have shown that the RSA application is problematic due to a variety of reasons including difficulties in outcome definition, monitoring and control of patient register, logistical setup, integration and interoperability of health information technology infrastructure. RSA may be helpful, but have not always been successful due to their inability to deal with dynamics in the market, which is highly relevant for oncology drugs.

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