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REAL WORLD EVIDENCE IN EUROPE - THE RESULTS OF AN EXPERT SURVEY

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OBJECTIVES: Interest in Real World Evidence (RWE), data not collected via traditional randomised controlled trials (RCT) used in different contexts, is increasing for market-access and reimbursement decision-makers. A global survey was undertaken to understand the use of RWE in these contexts. **METHODS:** The survey tool, 35 qualitative and quantitative open- and closed-ended questions, was developed iteratively with stakeholders (academia, health services, government bodies, patient organisations). The tool, available in English via Qualtrics from March 2017, included questions on the use of RWE for licensing and coverage recommendations, RWE ownership and the future of RWE. The survey was distributed to a selection of global contacts (n= 260). **RESULTS:** We analysed preliminary results for 46 returned surveys. Respondents were from 20 countries and a variety of roles (academia, HTA bodes, clinicians and patient organisations). Over two-thirds (69%, n=24) thought it unlikely RWE would support licensing and market authorisation-related decision-making, 91% (32) thought it more likely that RWE would have a role in national-level HTA periodic re-assessment. Less than 40% thought that RWE would ever play a similar role to RCT in drug evaluations, although 14 countries reported accepting lower levels of evidence for decision-making. Respondents from Spain, Russia, Cyprus, Bulgaria, Romania, France and the UK saw potential in the use of RWE in regulatory, reimbursement, and clinical based decision-making, economic evaluations and reassessment-re-review in the next 3-5 years. Those from Bosnia and Herzegovina, Belgium, Austria, Italy and Germany saw less potential. Barriers to RWE use included issues around lack of randomisation, lack of data availability and data quality. **CONCLUSIONS:** Whilst there are some differing opinions around the use of RWE for regulatory purposes, most respondents see it as a complement to RCT, rather than a replacement. The general opinion is that RWE will become more valuable over time if data quality and availability can be improved.