

Services to Support NICE and Other HTA Submissions

Early Benefit Assessment Dossiers

Gaining global market access for your products requires expertise in widely varied and constantly changing reimbursement environments. Our experts have experience contributing to successful NICE and other HTA submissions and can help you achieve the best result for your product.

We provide strategic input into the development and presentation of robust and compelling value arguments and analyses of clinical and economic data. We are knowledgeable about NICE processes; we prepared the first successful submission under the STA process when it was initially launched.

We can develop all components required for your submissions, including CU models, BIMs, systematic reviews of clinical and economic evidence, and meta-analyses, as well as full and partial dossiers. We also assist sponsors with responses to NICE during the consultation process.

Our HTA submission experience includes:

- National Institute of Clinical Excellence (NICE) UK
- · Scottish Medicines Consortium (SMC) Scotland
- All Wales Medicines Strategy Group (AWMSG) Wales
- National Centre for Pharmacoeconomics (NCPE) -Ireland
- The Dental and Pharmaceutical Benefits Agency (TLV) – Sweden
- Pharmaceutical Benefits Advisory Committee (PBAC)
 Australia
- Academy of Managed Care Pharmacy (AMCP) dossier – USA
- WellPoint (WP) dossier USA
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Federal Joint Commission, Gemeinsamer Bundesauschuss (G-BA) - Germany

STA Process Topic Selection Phase 1 Phase 2 Phase 3 and Scoping Press and customer statements FAD5 to Request for clarification begins 1 year before Submit submitted clarification invitation Request for partial or full begins FAD published resubmission several New timeline months published hefore Nomination of experts Week 1 Request for further clarification 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 28 29 30 31 32 33 34 35 36 37 38 39 beyond ACD Issued Week 39 Our Services Submissions from manufacturer/sponsor, health care ³ Positive Committee for Human Medicinal ⁵ Final Appraisal Determinations professionals, and patient/carer groups Products opinion required to proceed ⁶ 15 working days to appeal

⁴ Appraisal consultation document

Contact Us: info@rtihs.org www.rtihs.org

² Evidence Review Group