

RTI-HS Services to Support NICE Submissions

At RTI Health Solutions® (RTI-HS), we help our clients prepare and submit successful NICE submissions.

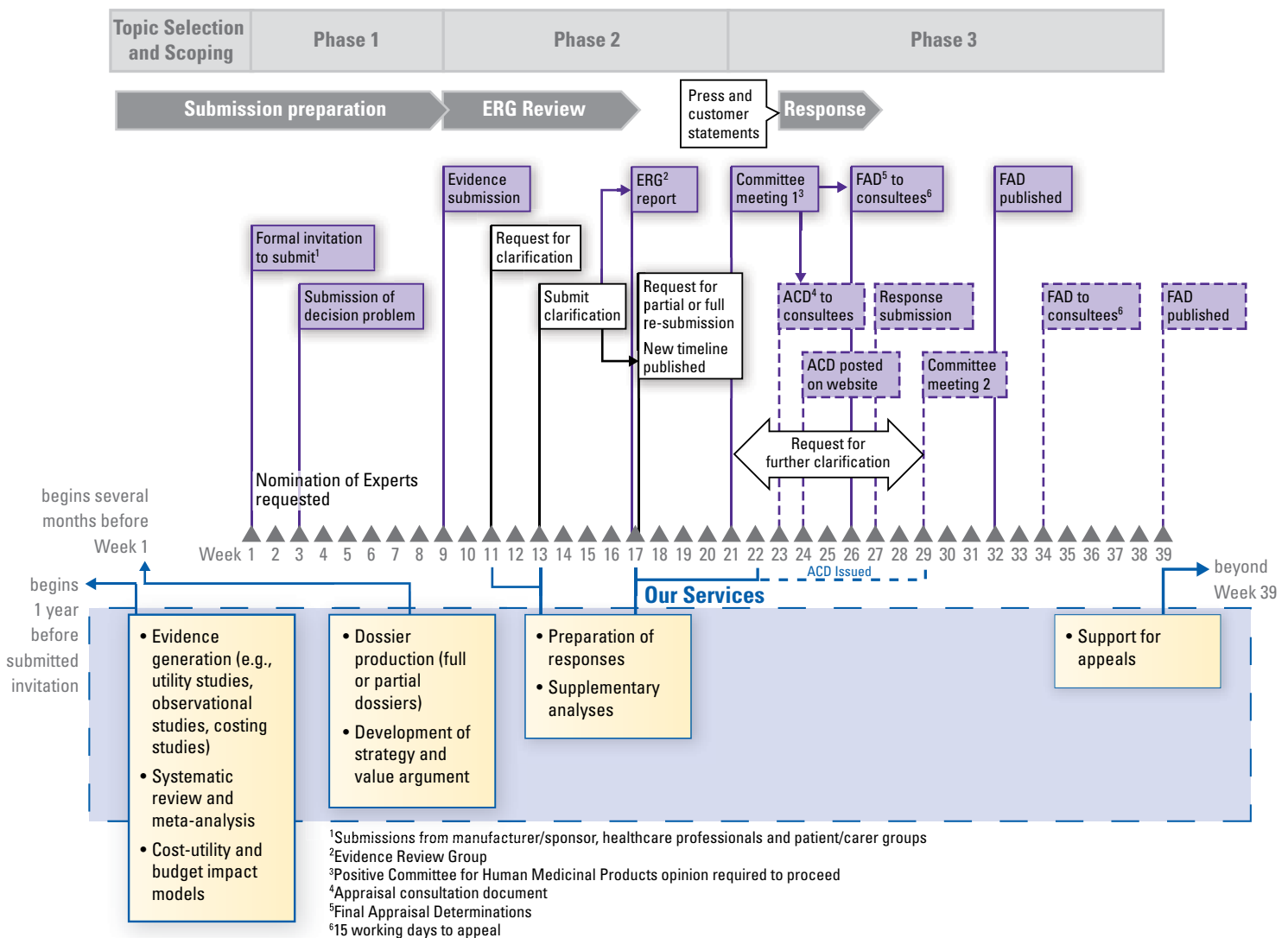
We provide strategic input into the presentation of value arguments and analyses of clinical, statistical and economic data. We are familiar with NICE processes, including the new Single Technology Appraisal (STA) process. In fact, we prepared the first submission under the STA process when it was first launched.

We have developed all components required for NICE submissions, including cost-utility models, budget impact models, systematic reviews of clinical and cost-effectiveness evidence, and meta-analyses, as well as full and partial dossiers. We also have assisted with responses to NICE during the consultation process.

We have experience in supporting formal HTA submissions in several markets:

- National Institute of Clinical Excellence (NICE) – UK
- Scottish Medicines Consortium (SMC) – Scotland
- All Wales Medicines Strategy Group (AWMSG) – Wales
- Academy of Managed Care Pharmacy (AMCP) dossier – USA
- WellPoint (WP) dossier – USA
- Tandvårds-och läkemedelsförmånsverket (TLV) – Sweden
- Pharmaceutical Benefits Advisory Committee (PBAC) – Australia
- Common Drug Review – Canadian Agency for Drugs and Technologies in Health (CADTH)
- Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) – Spain
- Dirección General de Farmacia y Productos Sanitarios (MSC) – Spain

STA Process



See How We've Helped with Successful Submissions

Docetaxel (Taxotere[®], Sanofi-Aventis) for Early Breast Cancer: First Submission to Be Reviewed Under the NICE Single Technology Appraisal (STA) Process

RTI-HS supported the NICE submission for docetaxel for early breast cancer. This was the first drug to be reviewed under NICE's Single Technology Appraisal (STA) process. As part of our support, we:

- Prepared the probabilistic, cost-utility submission model and budget impact estimates
- Provided strategic input and developed the full submission dossier using the new, more demanding STA dossier format
- Supported our client in preparing responses to the Institute, including an additional systematic review and economic analyses that were necessary to support the original submitted evidence

The final appraisal determination was published July 18, 2006. Taxotere was recommended within its licensed indication without restriction. Our model was also used in support of submissions to the SMC and PBAC; both agencies also recommended docetaxel within its licensed indication.

Dabigatran etexilate (Pradaxa[®], Boehringer Ingelheim GmbH) for the Prevention of Venous Thromboembolism

RTI-HS supported Boehringer Ingelheim (BI) in preparing the submission of dabigatran, a new oral anticoagulant for the prevention of venous thromboembolism after orthopedic surgery. As part of our support, we:

- Performed a meta-analysis of the phase III dabigatran trials and indirect comparisons of dabigatran with the range of alternative interventions available in major markets using a Bayesian mixed treatment comparison meta-analysis
- Developed a global probabilistic cost-utility model populated with UK data, plus a full technical report. The formal model specification and final

model were reviewed and validated by a panel of clinical experts to ensure clinical validity, and by BI representatives around the world to optimize coverage of the global needs of the model.

BI was able to prepare the STA submission internally using the materials we developed. We provided support by responding to specific technical queries. We performed, reported, and quality checked additional meta-analyses within the 2-week period available for the response. Additionally, we provided technical clarification and collaborated with the BI team to prepare the response to NICE.

Dabigatran was recommended by NICE within its licensed indication without the need for an appraisal consultation. The RTI-HS model was also used in support of other successful submissions for dabigatran, including approval by SMC. A review by CADTH is ongoing.

Fesoterodine (Toviaz[®], Pfizer) for Overactive Bladder

RTI-HS supported Pfizer in preparing the SMC submission for fesoterodine, an SNRI antidepressant, for the treatment of overactive bladder (OAB). As part of our support, we:

- Performed a systematic review of the clinical literature for treatments of OAB and used adjusted indirect meta-analyses to summarize the overall treatment effects
- Adapted a global probabilistic cost-utility model populated with data for the UK
- Led the preparation of the full clinical and economic SMC submission document
- Provided additional support during this process, responding to specific technical queries

Fesoterodine was recommended by the SMC (July 2008) for patients experiencing OAB symptoms (increased urinary frequency and/or urgency and/or urgency incontinence), without the need for additional clarifications or analyses.

Core RTI-HS Team Leading NICE Submissions

Based in Manchester, UK, RTI-HS has an expert team that leads NICE submission projects. Our team consists of persons with expertise in health economics, systematic reviews, biostatistics and dossier production, and includes individuals with experience at NICE. Core team members include the following:

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