

TIP SHEET



MARKET ACCESS FOR EARLY STAGE AND LATE STAGE DRUGS - UK

#LOOKINGAHEADOFTHECURVE



UNITED KINGDOM

EARLY STAGE DRUGS: WE RECOMMEND THAT MANUFACTURERS AND MARKETING COMPANIES:

1

Collect utility data in clinical trials, using recognized instruments, to help support required cost effectiveness modelling as they need to be available to support reimbursement. This is better done in Phase III studies instead of waiting until commercialization so that when the pricing discussions begin, the data would be available.

2

Consider whether to approach the HTA authority, NICE, for inclusion in an Early Access to Medicines Scheme (EAMS).

3

This is a good time to consider submitting your dossier for NICE review. NICE has been releasing COVID-19 rapid evidence summary guidelines since March 2020 for a range of health technology interventions for conditions associated with the pandemic and high priority drugs. During the pandemic, NICE has supported the system with these rapid guidelines and therapeutically critical guidance. From 1 June 2020, they restarted publication of guidance not related to COVID-19.

LATE STAGE DRUGS: FOR PRODUCTS THAT ARE CLOSER TO LAUNCH, WE RECOMMEND THAT MANUFACTURERS AND MARKETING COMPANIES:

1

Ensure financial accounting for the technology is within NHS profit allowances with no negative cross-portfolio impact. Calculating these allowances is quite technical and requires careful assessment in order to optimize revenues.

2

Develop evidence-supported Value Cases to support formulary enlistment at the local level.

WHY PARTNER WITH GIRS?

The GIRS International Beacon has over 17 years of experience developing market access strategies in EX-U.S., countries. We also assist with the implementation of these strategies in each country. For market access support, email us at info@girsinc.com or call us at 901-834-9119.