Objective

- To complement an RWD collection framework to be incorporated alongside the nivolumab-gastric cancer EAMS.

Methods

- Patient population: Patients with advanced or recurrent gastric or GEJ adenocarcinoma (GC/GEJ) who received two or more prior systemic therapies.
- Patients enrolled into EAMS from 01-Mar-16. Patients with gastric cancer have since been withdrawn from the GC/GEJ EAMS to protect patients.
- The majority of patients (78/87; 89.7%) who initially consented to EQ 5D questionnaire completion at baseline (prior to first treatment dose) and every two weeks following treatment initiation are still recalling.
- Within the GC/GEJ EAMS enrolment period, 131 patients initiated treatment with nivolumab.
- Seven of these sites (14.3%) identified by official confirmation of capacity and capability were not required for sites to participate in RWD collection.
- The majority of sites (90.5%) enrolling one or more patients into EAMS also had a patient information sheet developed.
- Medical chart review: This study followed standard RWD collection methodology, however, it had several limitations. In particular, collection of certain elements was not always feasible.

Results (Cont’d)

- Eighty-seven (66.4) patients into GC/GEJ EAMS had also consented to EQ 5D questionnaire completion at baseline (prior to first treatment dose) and every two weeks following treatment initiation are still recalling.
- Within the GC/GEJ EAMS enrolment period, 131 patients initiated treatment with nivolumab.
- The majority of sites (90.5%) enrolling one or more patients into EAMS also had a patient information sheet developed.
- Medical chart review: This study followed standard RWD collection methodology, however, it had several limitations. In particular, collection of certain elements was not always feasible.

Conclusions

- This GC/GEJ EAMS program has not only provided an innovative medical intervention to patients with gastric/GEJ cancer, but also allowed for other aspects of the EAMS to evolve.
- It has allowed investigation of quality of life outcomes (EQ 5D).
- Conclusions
- An innovative medical intervention in patients with advanced or recurrent GC/GEJ cancer has now been withdrawn from the GC/GEJ EAMS.
- The majority of sites (90.5%) enrolling one or more patients into EAMS also had a patient information sheet developed.
- Medical chart review: This study followed standard RWD collection methodology, however, it had several limitations. In particular, collection of certain elements was not always feasible.

References


Acknowledgments

We would like to thank all the stakeholders that made setting up this framework possible. In particular, we would like to acknowledge the contribution of the Evidera team (Mira Musingarimi, Christopher Kiff, Meng Wang, Adenike Amadi, David Tayas). We would also like to thank the site research and development (R&D) teams for their cooperation during this study. We would also like to thank the Evidera team (Mira Musingarimi, Christopher Kiff, Meng Wang, Adenike Amadi, David Tayas). We would also like to thank the Evidera team (Mira Musingarimi, Christopher Kiff, Meng Wang, Adenike Amadi, David Tayas).

PRM18

Real-World Data (RWD) Collection Alongside Early Access to Medicines Schemes (EAMS) - Nivolumab in Gastric or Gastroesophageal Junction Adenocarcinoma (GC/GEJ) After Two or More Prior Therapies

Christopher Kiff1; Meng Wang2; Adenike Amadi3; David Tayas4; 1Bristol Myers Squibb, London, GB

Presenting Author Email: david.tayas@bms.com

Clarity with patient consent obtained through Quick Response Code (QR) and face-to-face message for personal data which may be not required without written consent of the author.

Background

- The Early Access to Medicine Scheme (EAMS), governed by the Medicines and Healthcare Products Regulatory Agency (MHRA), was established in 2016 to promote access to highly innovative medicines that do not have marketing authorisation but address a significant unmet medical need.
- The EAMS program is currently the only one of its kind to have issued guidelines for systematic collection of real-world data (RWD) and asserts the importance of collecting RWD to provide additional evidence of product value outside of a clinical trial setting.
- The MHRA guidance highlights that data generated in EAMS can be used to facilitate Health Technology Assessment (HTA) submissions (e.g., those run by the National Institute for Health and Care Excellence [NICE] and Cancer Drugs Fund panels). These guidelines suggest that EAMS data can also be used to inform post-market surveillance.
- Requirements for additional data collection (e.g., quality of life) in EAMS must be agreed upon by all parties including patients and, in a case-by-case basis, and currently there is no framework for incorporating this.
- The use of EAMS is a market access strategy to generate additional evidence to enable conduct of additional data collection in EAMS will be beneficial to improve validity of this research for regulatory submission.

Results

- RWD collection framework (cont.):
  - The level of effort and workload needed to collect the additional RWD data was carefully considered. Data collection at two time points early post-treatment was kept to a key data outcome (e.g., disease progression, survival status). Having physicians refer electron medical data through the same data collection tool for other aspects of the EAMS increased overall burden of data.
  - EQ-SD data collection was designed to be completed every two weeks, in line with clinic visits for nivolumab initiation. The timing/chose as a reminder to complete the questionnaire and increases the chance that the questionnaire would be posted. Patients were sent home with an EQ-SD package at enrolment and mailed their responses to the response clinical research organization (RCR), for collection and processing which further reduced any burden to the site.
  - Adverse event (AE) monitoring outside of the clinical trial setting was an important consideration.

Figure 1. Data collection in EAMS

Figure 2. Steps to incorporate RWD collection in EAMS

Figure 3. Schematic of RWD collection in GC/GEJ nivolumab EAMS

Table 1. Patient Enrollment and EQ-SD Compliance in EAMS

<table>
<thead>
<tr>
<th>Patient Status</th>
<th>% (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient enrolled in EAMS and had at least one dose of nivolumab</td>
<td>131 (100)</td>
</tr>
<tr>
<td>Patient did not consent to any component of new real-world data collection</td>
<td>17 (13.9)</td>
</tr>
<tr>
<td>Patient consented to medical chart review only</td>
<td>27 (20.6)</td>
</tr>
<tr>
<td>Patient consented to EQ-SD completion</td>
<td>87 (67.4)</td>
</tr>
<tr>
<td>Patient completed baseline EQ-5D questionnaire</td>
<td>78 (59.7)</td>
</tr>
<tr>
<td>Patient completed baseline and at least one follow-up EQ-SD questionnaire</td>
<td>68 (57.2)</td>
</tr>
</tbody>
</table>

Figure 4. Steps to incorporate RWD collection in EAMS