

**eTable 1 Details of events classified as IME**

|   |                                   |   |
|---|-----------------------------------|---|
| Arthralgia  | Duodenal ulcer                    | Pancreatitis  |
| Atrial fibrillation*  | Facial paresis                    | Pneumonia   |
| Cellulitis  | Hospitalisation for arthritis     | Pneumonia and Lower respiratory tract infection                         |
| Cholecystitis, Abdominal pain, Cholecystectomy, Intestinal obstruction and Pancreatitis | Hypersensitivity                  | Pneumonia, Lower respiratory tract infection, Gastroenteritis and Death |
| Cholecystitis infective   | Intestinal perforation            | Pneumonia and Vasculitis  |
| Chronic obstructive pulmonary disease   | Lower respiratory tract infection | Sudden hearing loss   |
| Chronic obstructive pulmonary disease   | Meniere's disease                 | Thrombocytopenia, Mantle cell lymphoma and Death                        |
| Colitis   | Multi-organ failure and Death     |   |
| Crohn's disease and Abdominal infection   | Nasal polyps and Swelling         |   |

IME=immunologically-mediated events.

\* Other instances of AF were classified as OTH; this instance, which arose in conjunction with diarrhoea and weight loss, was classified as OTH by one assessor and IME by a second assessor with a consensus classification of IME.