

| Obs | title | subjectsAffectedBySeriousAdverseEvents | subjectsAffectedByNonSeriousAdverseEvents |
|-----|--------------|--|---|
| 1 | Control | 15 | 15 |
| 2 | Experimental | 32 | 24 |

| Obs | deathsResultingFromAdverseEvents | subjectsExposed | deathsAllCauses |
|-----|----------------------------------|-----------------|-----------------|
| 1 | 9 | 60 | 9 |
| 2 | 22 | 67 | 22 |

| Obs | term | title | occurrences | occurrencesCausallyRelatedToTreatment | deaths |
|-----|------------------------------|--------------|-------------|---------------------------------------|--------|
| 1 | B-cell lymphoma | Control | 1 | 0 | 0 |
| 2 | B-cell lymphoma | Experimental | 0 | 0 | 0 |
| 3 | Cardiac arrest | Control | 1 | 0 | 1 |
| 4 | Cardiac arrest | Experimental | 0 | 0 | 0 |
| 5 | Cardiac failure congestive | Control | 0 | 0 | 0 |
| 6 | Cardiac failure congestive | Experimental | 1 | 0 | 0 |
| 7 | Abdominal pain | Control | 1 | 0 | 0 |
| 8 | Abdominal pain | Experimental | 0 | 0 | 0 |
| 9 | Gastroenteritis viral | Control | 0 | 0 | 0 |
| 10 | Gastroenteritis viral | Experimental | 1 | 0 | 1 |
| 11 | Gastrointestinal haemorrhage | Control | 0 | 0 | 0 |
| 12 | Gastrointestinal haemorrhage | Experimental | 1 | 0 | 1 |
| 13 | Oesophageal spasm | Control | 0 | 0 | 0 |
| 14 | Oesophageal spasm | Experimental | 1 | 0 | 1 |
| 15 | Oesophagitis | Control | 0 | 0 | 0 |
| 16 | Oesophagitis | Experimental | 1 | 0 | 0 |
| 17 | Chest pain | Control | 0 | 0 | 0 |
| 18 | Chest pain | Experimental | 1 | 0 | 0 |

| Obs | deathsCausallyRelatedToTreatment | subjectsAffected | eutctid |
|-----|----------------------------------|------------------|--------------|
| 1 | 0 | 1 | 100000004851 |
| 2 | 0 | 0 | 100000004851 |
| 3 | 0 | 1 | 100000004849 |
| 4 | 0 | 0 | 100000004849 |
| 5 | 0 | 0 | 100000004849 |
| 6 | 0 | 1 | 100000004849 |
| 7 | 0 | 1 | 100000004856 |
| 8 | 0 | 0 | 100000004856 |
| 9 | 0 | 0 | 100000004856 |
| 10 | 0 | 1 | 100000004856 |
| 11 | 0 | 0 | 100000004856 |
| 12 | 0 | 1 | 100000004856 |
| 13 | 0 | 0 | 100000004856 |
| 14 | 0 | 1 | 100000004856 |
| 15 | 0 | 0 | 100000004856 |
| 16 | 0 | 1 | 100000004856 |
| 17 | 0 | 0 | 100000004867 |
| 18 | 0 | 1 | 100000004867 |

| Obs | term | title | occurrences | occurrencesCausallyRelatedToTreatment | deaths |
|-----|---------------------------------|--------------|-------------|---------------------------------------|--------|
| 19 | Cholecystitis acute | Control | 1 | 0 | 0 |
| 20 | Cholecystitis acute | Experimental | 1 | 0 | 0 |
| 21 | Pulmonary vasculitis | Control | 1 | 0 | 0 |
| 22 | Pulmonary vasculitis | Experimental | 0 | 0 | 0 |
| 23 | Vasculitis | Control | 1 | 0 | 1 |
| 24 | Vasculitis | Experimental | 2 | 0 | 2 |
| 25 | Cellulitis | Control | 0 | 0 | 0 |
| 26 | Cellulitis | Experimental | 1 | 1 | 1 |
| 27 | Escherichia urinary tract infec | Control | 1 | 0 | 1 |
| 28 | Escherichia urinary tract infec | Experimental | 0 | 0 | 0 |
| 29 | Gastroenteritis Escherichia col | Control | 0 | 0 | 0 |
| 30 | Gastroenteritis Escherichia col | Experimental | 1 | 0 | 1 |
| 31 | Influenza | Control | 0 | 0 | 0 |
| 32 | Influenza | Experimental | 1 | 0 | 1 |
| 33 | Lower respiratory tract infecti | Control | 1 | 1 | 1 |
| 34 | Lower respiratory tract infecti | Experimental | 0 | 0 | 0 |
| 35 | Pneumonia | Control | 0 | 0 | 0 |
| 36 | Pneumonia | Experimental | 3 | 3 | 1 |

| Obs | deathsCausallyRelatedToTreatment | subjectsAffected | eutctid |
|-----|----------------------------------|------------------|--------------|
| 19 | 0 | 1 | 100000004871 |
| 20 | 0 | 1 | 100000004871 |
| 21 | 0 | 1 | 100000004870 |
| 22 | 0 | 0 | 100000004870 |
| 23 | 0 | 1 | 100000004870 |
| 24 | 0 | 2 | 100000004870 |
| 25 | 0 | 0 | 100000004862 |
| 26 | 1 | 1 | 100000004862 |
| 27 | 0 | 1 | 100000004862 |
| 28 | 0 | 0 | 100000004862 |
| 29 | 0 | 0 | 100000004862 |
| 30 | 0 | 1 | 100000004862 |
| 31 | 0 | 0 | 100000004862 |
| 32 | 0 | 1 | 100000004862 |
| 33 | 1 | 1 | 100000004862 |
| 34 | 0 | 0 | 100000004862 |
| 35 | 0 | 0 | 100000004862 |
| 36 | 1 | 3 | 100000004862 |

| Obs | term | title | occurrences | occurrencesCausallyRelatedToTreatment | deaths |
|-----|------------------------------|--------------|-------------|---------------------------------------|--------|
| 37 | Respiratory tract infection | Control | 0 | 0 | 0 |
| 38 | Respiratory tract infection | Experimental | 2 | 1 | 2 |
| 39 | Urinary tract infection | Control | 0 | 0 | 0 |
| 40 | Urinary tract infection | Experimental | 2 | 1 | 1 |
| 41 | Fall | Control | 0 | 0 | 0 |
| 42 | Fall | Experimental | 1 | 0 | 0 |
| 43 | Post procedural complication | Control | 0 | 0 | 0 |
| 44 | Post procedural complication | Experimental | 1 | 0 | 1 |
| 45 | Medical observation | Control | 0 | 0 | 0 |
| 46 | Medical observation | Experimental | 1 | 0 | 1 |
| 47 | Hyperglycaemia | Control | 1 | 0 | 1 |
| 48 | Hyperglycaemia | Experimental | 0 | 0 | 0 |
| 49 | Hyperkalaemia | Control | 0 | 0 | 0 |
| 50 | Hyperkalaemia | Experimental | 1 | 0 | 0 |
| 51 | Bladder papilloma | Control | 0 | 0 | 0 |
| 52 | Bladder papilloma | Experimental | 1 | 0 | 0 |
| 53 | Cerebrovascular accident | Control | 1 | 0 | 1 |
| 54 | Cerebrovascular accident | Experimental | 0 | 0 | 0 |

| Obs | deathsCausallyRelatedToTreatment | subjectsAffected | eutctId |
|-----|----------------------------------|------------------|--------------|
| 37 | 0 | 0 | 100000004862 |
| 38 | 1 | 2 | 100000004862 |
| 39 | 0 | 0 | 100000004862 |
| 40 | 1 | 1 | 100000004862 |
| 41 | 0 | 0 | 100000004863 |
| 42 | 0 | 1 | 100000004863 |
| 43 | 0 | 0 | 100000004863 |
| 44 | 0 | 1 | 100000004863 |
| 45 | 0 | 0 | 100000004848 |
| 46 | 0 | 1 | 100000004848 |
| 47 | 0 | 1 | 100000004861 |
| 48 | 0 | 0 | 100000004861 |
| 49 | 0 | 0 | 100000004861 |
| 50 | 0 | 1 | 100000004861 |
| 51 | 0 | 0 | 100000004864 |
| 52 | 0 | 1 | 100000004864 |
| 53 | 0 | 1 | 100000004852 |
| 54 | 0 | 0 | 100000004852 |

| Obs | term | title | occurrences | occurrencesCausallyRelatedToTreatment | deaths |
|-----|--------------------------|--------------|-------------|---------------------------------------|--------|
| 55 | Sleep apnoea syndrome | Control | 1 | 0 | 1 |
| 56 | Sleep apnoea syndrome | Experimental | 0 | 0 | 0 |
| 57 | Conversion disorder | Control | 0 | 0 | 0 |
| 58 | Conversion disorder | Experimental | 1 | 1 | 1 |
| 59 | Proteinuria | Control | 0 | 0 | 0 |
| 60 | Proteinuria | Experimental | 1 | 0 | 0 |
| 61 | Laryngeal stenosis | Control | 0 | 0 | 0 |
| 62 | Laryngeal stenosis | Experimental | 4 | 0 | 1 |
| 63 | Pneumomediastinum | Control | 0 | 0 | 0 |
| 64 | Pneumomediastinum | Experimental | 1 | 0 | 0 |
| 65 | Pneumonia klebsiella | Control | 0 | 0 | 0 |
| 66 | Pneumonia klebsiella | Experimental | 1 | 1 | 1 |
| 67 | Pneumonia staphylococcal | Control | 0 | 0 | 0 |
| 68 | Pneumonia staphylococcal | Experimental | 1 | 1 | 1 |
| 69 | Pneumonia viral | Control | 1 | 0 | 1 |
| 70 | Pneumonia viral | Experimental | 0 | 0 | 0 |
| 71 | Pulmonary embolism | Control | 0 | 0 | 0 |
| 72 | Pulmonary embolism | Experimental | 1 | 0 | 0 |

| Obs | deathsCausallyRelatedToTreatment | subjectsAffected | eutctid |
|-----|----------------------------------|------------------|--------------|
| 55 | 0 | 1 | 100000004852 |
| 56 | 0 | 0 | 100000004852 |
| 57 | 0 | 0 | 100000004873 |
| 58 | 1 | 1 | 100000004873 |
| 59 | 0 | 0 | 100000004857 |
| 60 | 0 | 1 | 100000004857 |
| 61 | 0 | 0 | 100000004855 |
| 62 | 0 | 2 | 100000004855 |
| 63 | 0 | 0 | 100000004855 |
| 64 | 0 | 1 | 100000004855 |
| 65 | 0 | 0 | 100000004855 |
| 66 | 1 | 1 | 100000004855 |
| 67 | 0 | 0 | 100000004855 |
| 68 | 1 | 1 | 100000004855 |
| 69 | 0 | 1 | 100000004855 |
| 70 | 0 | 0 | 100000004855 |
| 71 | 0 | 0 | 100000004855 |
| 72 | 0 | 1 | 100000004855 |

| Obs | term | title | occurrences | occurrencesCausallyRelatedToTreatment | deaths |
|-----|----------------------------|--------------|-------------|---------------------------------------|--------|
| 73 | Aortic valve replacement | Control | 1 | 0 | 0 |
| 74 | Aortic valve replacement | Experimental | 0 | 0 | 0 |
| 75 | Cholecystectomy | Control | 0 | 0 | 0 |
| 76 | Cholecystectomy | Experimental | 1 | 0 | 0 |
| 77 | Dacryocystorhinostomy | Control | 0 | 0 | 0 |
| 78 | Dacryocystorhinostomy | Experimental | 1 | 0 | 0 |
| 79 | Hip arthroplasty | Control | 1 | 0 | 1 |
| 80 | Hip arthroplasty | Experimental | 2 | 0 | 2 |
| 81 | Small intestinal resection | Control | 0 | 0 | 0 |
| 82 | Small intestinal resection | Experimental | 1 | 0 | 1 |
| 83 | Deep vein thrombosis | Control | 1 | 0 | 1 |
| 84 | Deep vein thrombosis | Experimental | 3 | 0 | 2 |
| 85 | Pulmonary embolism | Control | 1 | 0 | 0 |
| 86 | Pulmonary embolism | Experimental | 1 | 0 | 1 |

| Obs | deathsCausallyRelatedToTreatment | subjectsAffected | eutctId |
|-----|----------------------------------|------------------|--------------|
| 73 | 0 | 1 | 100000004865 |
| 74 | 0 | 0 | 100000004865 |
| 75 | 0 | 0 | 100000004865 |
| 76 | 0 | 1 | 100000004865 |
| 77 | 0 | 0 | 100000004865 |
| 78 | 0 | 1 | 100000004865 |
| 79 | 0 | 1 | 100000004865 |
| 80 | 0 | 2 | 100000004865 |
| 81 | 0 | 0 | 100000004865 |
| 82 | 0 | 1 | 100000004865 |
| 83 | 0 | 1 | 100000004866 |
| 84 | 0 | 3 | 100000004866 |
| 85 | 0 | 1 | 100000004866 |
| 86 | 0 | 1 | 100000004866 |

| Obs | term | title | occurrences | subjectsAffected | eutctId |
|-----|---------------------------------|--------------|-------------|------------------|--------------|
| 1 | Neutropenia | Control | 0 | 0 | 100000004851 |
| 2 | Neutropenia | Experimental | 1 | 1 | 100000004851 |
| 3 | Acute coronary syndrome | Control | 1 | 1 | 100000004849 |
| 4 | Acute coronary syndrome | Experimental | 0 | 0 | 100000004849 |
| 5 | Acute myocardial infarction | Control | 0 | 0 | 100000004849 |
| 6 | Acute myocardial infarction | Experimental | 1 | 1 | 100000004849 |
| 7 | Angina pectoris | Control | 0 | 0 | 100000004849 |
| 8 | Angina pectoris | Experimental | 1 | 1 | 100000004849 |
| 9 | Atrial fibrillation | Control | 0 | 0 | 100000004849 |
| 10 | Atrial fibrillation | Experimental | 1 | 1 | 100000004849 |
| 11 | Atrioventricular block complete | Control | 0 | 0 | 100000004849 |
| 12 | Atrioventricular block complete | Experimental | 1 | 1 | 100000004849 |
| 13 | Abdominal pain | Control | 0 | 0 | 100000004856 |
| 14 | Abdominal pain | Experimental | 1 | 1 | 100000004856 |
| 15 | Duodenal ulcer | Control | 0 | 0 | 100000004856 |
| 16 | Duodenal ulcer | Experimental | 1 | 1 | 100000004856 |
| 17 | Intestinal perforation | Control | 1 | 1 | 100000004856 |
| 18 | Intestinal perforation | Experimental | 0 | 0 | 100000004856 |
| 19 | Pyrexia | Control | 1 | 1 | 100000004867 |
| 20 | Pyrexia | Experimental | 1 | 1 | 100000004867 |
| 21 | Cholecystitis | Control | 0 | 0 | 100000004871 |
| 22 | Cholecystitis | Experimental | 1 | 1 | 100000004871 |
| 23 | Drug hypersensitivity | Control | 0 | 0 | 100000004870 |
| 24 | Drug hypersensitivity | Experimental | 1 | 1 | 100000004870 |
| 25 | Hypersensitivity | Control | 0 | 0 | 100000004870 |
| 26 | Hypersensitivity | Experimental | 1 | 1 | 100000004870 |
| 27 | Vasculitis | Control | 4 | 3 | 100000004870 |
| 28 | Vasculitis | Experimental | 3 | 3 | 100000004870 |
| 29 | Escherichia urinary tract infec | Control | 0 | 0 | 100000004862 |
| 30 | Escherichia urinary tract infec | Experimental | 1 | 1 | 100000004862 |
| 31 | Influenza | Control | 0 | 0 | 100000004862 |
| 32 | Influenza | Experimental | 1 | 1 | 100000004862 |
| 33 | Pneumonia | Control | 2 | 2 | 100000004862 |
| 34 | Pneumonia | Experimental | 4 | 3 | 100000004862 |
| 35 | Pneumonia pseudomonal | Control | 0 | 0 | 100000004862 |
| 36 | Pneumonia pseudomonal | Experimental | 1 | 1 | 100000004862 |
| 37 | Respiratory tract infection | Control | 2 | 2 | 100000004862 |
| 38 | Respiratory tract infection | Experimental | 1 | 1 | 100000004862 |

| Obs | term | title | occurrences | subjectsAffected | eutctId |
|-----|---------------------------------|--------------|-------------|------------------|--------------|
| 39 | Sinusitis | Control | 0 | 0 | 100000004862 |
| 40 | Sinusitis | Experimental | 1 | 1 | 100000004862 |
| 41 | Urinary tract infection | Control | 0 | 0 | 100000004862 |
| 42 | Urinary tract infection | Experimental | 1 | 1 | 100000004862 |
| 43 | Wound dehiscence | Control | 0 | 0 | 100000004863 |
| 44 | Wound dehiscence | Experimental | 1 | 1 | 100000004863 |
| 45 | Dehydration | Control | 0 | 0 | 100000004861 |
| 46 | Dehydration | Experimental | 1 | 1 | 100000004861 |
| 47 | Osteoarthritis | Control | 0 | 0 | 100000004859 |
| 48 | Osteoarthritis | Experimental | 1 | 1 | 100000004859 |
| 49 | Anal squamous cell carcinoma | Control | 0 | 0 | 100000004864 |
| 50 | Anal squamous cell carcinoma | Experimental | 1 | 1 | 100000004864 |
| 51 | Squamous cell carcinoma | Control | 1 | 1 | 100000004864 |
| 52 | Squamous cell carcinoma | Experimental | 0 | 0 | 100000004864 |
| 53 | Sleep apnoea syndrome | Control | 2 | 1 | 100000004852 |
| 54 | Sleep apnoea syndrome | Experimental | 0 | 0 | 100000004852 |
| 55 | Enterovesical fistula | Control | 0 | 0 | 100000004857 |
| 56 | Enterovesical fistula | Experimental | 1 | 1 | 100000004857 |
| 57 | Renal impairment | Control | 1 | 1 | 100000004857 |
| 58 | Renal impairment | Experimental | 0 | 0 | 100000004857 |
| 59 | Bronchospasm | Control | 0 | 0 | 100000004855 |
| 60 | Bronchospasm | Experimental | 1 | 1 | 100000004855 |
| 61 | Dyspnoea | Control | 0 | 0 | 100000004855 |
| 62 | Dyspnoea | Experimental | 1 | 1 | 100000004855 |
| 63 | Laryngeal stenosis | Control | 1 | 1 | 100000004855 |
| 64 | Laryngeal stenosis | Experimental | 1 | 1 | 100000004855 |
| 65 | Lower respiratory tract infecti | Control | 1 | 1 | 100000004855 |
| 66 | Lower respiratory tract infecti | Experimental | 0 | 0 | 100000004855 |
| 67 | Lung adenocarcinoma | Control | 1 | 1 | 100000004855 |
| 68 | Lung adenocarcinoma | Experimental | 0 | 0 | 100000004855 |
| 69 | Pneumonia | Control | 1 | 1 | 100000004855 |
| 70 | Pneumonia | Experimental | 0 | 0 | 100000004855 |
| 71 | Pneumonia streptococcal | Control | 0 | 0 | 100000004855 |
| 72 | Pneumonia streptococcal | Experimental | 1 | 1 | 100000004855 |
| 73 | Pneumonitis | Control | 1 | 1 | 100000004855 |
| 74 | Pneumonitis | Experimental | 0 | 0 | 100000004855 |
| 75 | Respiratory failure | Control | 0 | 0 | 100000004855 |
| 76 | Respiratory failure | Experimental | 1 | 1 | 100000004855 |

| Obs | term | title | occurrences | subjectsAffected | eutctId |
|-----|----------------------|--------------|-------------|------------------|--------------|
| 77 | Colostomy closure | Control | 0 | 0 | 100000004865 |
| 78 | Colostomy closure | Experimental | 1 | 1 | 100000004865 |
| 79 | Aortic dissection | Control | 0 | 0 | 100000004866 |
| 80 | Aortic dissection | Experimental | 1 | 1 | 100000004866 |
| 81 | Deep vein thrombosis | Control | 0 | 0 | 100000004866 |
| 82 | Deep vein thrombosis | Experimental | 1 | 1 | 100000004866 |