

| 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 |
|-----|------------------------------|--------------|-------------|---------------------------------------|--------|
| 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 |