

Table S1. Progression free survival (PFS)(PP set=140 patients)

| | CIK immunotherapy group (N=69) | Control group (N=71) |
|-------------------------------------|-----------------------------------|-------------------------|
| Incidence rate (Death or PD), n(%) | 60(86.957%) | 61(85.915%) |
| PD, n(%) | 59(85.507%) | 60(84.507%) |
| Death, n(%) | 1(1.449%) | 1(1.408%) |
| Progression-Free survival rate (%) | | |
| 12 months(%) [95% CI] | 28.99 [18.85, 39.89] | 19.72 [11.44, 29.64] |
| 18 months(%) [95% CI] | 26.09 [16.43, 36.79] | 18.08[11.44, 29.64] |
| 24 months(%) [95% CI] | 18.31 [10.15, 28.37] | 12.65 [5.95, 22.00] |
| Progression-Free survival, Mean±SE | 13.252±1.533 | 7.700±0.760 |
| 75% PFS [95% CI] | 19.243 [9.737, 26.447] | 8.586 [8.026, 19.474] |
| 50% PFS [95% CI] | 8.092 [7.072, 8.882] | 5.362 [3.980, 7.928] |
| 25% PFS [95% CI] | 5.263 [2.697, 5.822] | 2.467 [2.336, 2.763] |
| p-value ¹⁾ | 0.0218# | |
| Hazard ratio [90% CI] ²⁾ | 0.693 [0.512, 0.937] | |

* Progression-free survival=Diagnosis date of disease progression by MRI, date of death or date of off-study - Randomization date

¹⁾ Results by one-sided Log-rank test

²⁾ Presented as the result of one-sided test

P-value<0.05

Table S2. Overall survival (OS)(PP set=140 patients)

| | CIK immunotherapy group (N=69) | Control group (N=71) |
|-------------------------------------|-----------------------------------|-------------------------|
| Incidence rate(Death), n(%) | 42(60.870%) | 43(60.563%) |
| Overall Survival rate(%) | | |
| 12 months(%) [95% CI] | 80.54 [68.86, 88.21] | 76.34 [64.30, 84.79] |
| 18 months(%) [95% CI] | 59.41[46.29, 70.33] | 43.62[31.11, 55.46] |
| 24 months(%) [95% CI] | 40.92 [28.26, 53.16] | 39.56 [27.21, 51.64] |
| Survival, Mean±SE | 22.669±1.329 | 19.945±1.198 |
| 75% Survival [95% CI] | - [28.586, -] | - [25.428, -] |
| 50% Survival [95% CI] | 23.059 [17.204, 28.586] | 16.875 [13.915, 24.211] |
| 25% Survival [95% CI] | 14.276 [9.013, 17.204] | 12.007 [10.526, 13.651] |
| p-value ¹⁾ | | 0.4221 |
| Hazard ratio [90% CI] ²⁾ | | 0.840 [0.548, 1.287] |

* Overall Survival=Date of death or date of off-study - Randomization date

¹⁾ Results by Log-rank test

²⁾ Presented as the result of one-sided test

Table S3. Response Rate(Objective Response rate, Disease Control Rate)

Treatment response rate

| Treatment response | CIK group | | 95% C.I. | | Control group | | 95% C.I. | | p-value |
|-------------------------|-----------|----------|----------|---------|---------------|----------|----------|---------|----------------|
| | n | (%) | [min, | max] | n | (%) | [min, | max] | |
| ITT set | N= 91 | | | | N= 89 | | | | |
| n | 85 | | | | 82 | | | | |
| ORR | 23 | (27.059) | [17.610, | 36.500] | 13 | (15.854) | [7.950, | 23.760] | 0.0783+ |
| DCR | 70 | (82.353) | [74.250, | 90.460] | 52 | (63.415) | [52.990, | 73.840] | 0.0058+ |
| Complete response(CR) | 7 | (8.235) | | | 4 | (4.878) | | | |
| Partial response(PR) | 16 | (18.824) | | | 9 | (10.976) | | | |
| No change(NC) | 47 | (55.294) | | | 39 | (47.561) | | | |
| Progressive disease(PD) | 15 | (17.647) | | | 30 | (36.585) | | | |

ORR=CR+PR

DCR=CR+PR+SD

t: Pearson's chi-square test

| | | | | | | | | | | | | | | | | |
|-------------------|-----------|-----|----------|-----|----------|-----|----------|-----|----------|-----|----------|-----|----------|-----|----------|-----|
| Arthralgia | 6(7.059) | [6] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 8(9.412) | [8] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Back pain | 9(10.588) | [9] | 2(2.353) | [2] | 1(1.177) | [1] | 1(1.177) | [1] | 5(5.882) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Myalgia | 5(5.882) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Muscular weakness | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Neck pain | 4(4.706) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Flank pain | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |

| | | | | | | | | | | | | | | | | |
|--|-------------------|-------------|-------------------|-------------|-------------------|-------------|-----------------|------------|-------------------|-------------|-----------------|------------|-----------------|------------|-----------------|------------|
| Clostridium test positive | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Electrocardiogram QT prolonged | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Electrocardiogram T wave abnormal | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Lymphocyte count decreased | 1(1.177) | [1] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Respiratory, thoracic and mediastinal disorders | 28(32.941) | [46] | 3(3.529) | [4] | 3(3.529) | [4] | 0(0.000) | [0] | 21(24.706) | [33] | 2(2.353) | [2] | 1(1.177) | [1] | 1(1.176) | [1] |
| Cough | 9(10.588) | [9] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 7(8.235) | [8] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Dyspnoea | 9(10.588) | [11] | 2(2.353) | [2] | 2(2.353) | [2] | 0(0.000) | [0] | 5(5.882) | [5] | 1(1.177) | [1] | 0(0.000) | [0] | 1(1.176) | [1] |
| Productive cough | 9(10.588) | [9] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 4(4.706) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Oropharyngeal pain | 5(5.882) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Rhinorrhoea | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hiccups | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [5] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] |
| Epistaxis | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Aspiration | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Atelectasis | 1(1.177) | [1] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Bronchitis chronic | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Dyspnoea exertional | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Emphysema | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Haemoptysis | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Increased bronchial secretion | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Pneumonia aspiration | 1(1.177) | [1] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Pneumothorax | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Pulmonary hypertension | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Pulmonary oedema | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Rhinitis allergic | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Sleep apnoea syndrome | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Blood and lymphatic system disorders | 24(28.235) | [58] | 10(11.765) | [18] | 10(11.765) | [16] | 1(1.177) | [2] | 16(18.824) | [30] | 4(4.706) | [5] | 4(4.706) | [5] | 0(0.000) | [0] |
| Thrombocytopenia | 13(15.294) | [15] | 2(2.353) | [2] | 1(1.177) | [1] | 1(1.177) | [1] | 12(14.118) | [13] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] |

| | | | | | | | | | | | | | | | | |
|--|-------------------|-------------|-----------------|------------|-----------------|------------|-----------------|------------|-------------------|-------------|-----------------|------------|-----------------|------------|-----------------|------------|
| Leukopenia | 16(18.824) | [26] | 2(2.353) | [2] | 1(1.177) | [1] | 1(1.177) | [1] | 7(8.235) | [8] | 2(2.353) | [2] | 2(2.353) | [2] | 0(0.000) | [0] |
| Neutropenia | 4(4.706) | [8] | 3(3.529) | [7] | 3(3.529) | [7] | 0(0.000) | [0] | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Lymphopenia | 4(4.706) | [6] | 4(4.706) | [5] | 4(4.706) | [5] | 0(0.000) | [0] | 2(2.353) | [3] | 1(1.177) | [2] | 1(1.177) | [2] | 0(0.000) | [0] |
| Anaemia | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Disseminated intravascular coagulation | 2(2.353) | [2] | 2(2.353) | [2] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Splenomegaly | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Eye disorders | 19(22.353) | [21] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | (24.706) | [26] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Dry eye | 6(7.059) | [6] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Eye pain | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 6(7.059) | [6] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Diplopia | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Eyelid oedema | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 4(4.706) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Visual impairment | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Conjunctivitis | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Foreign body sensation in eyes | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Ocular hyperaemia | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Vision blurred | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Cataract | 1(1.177) | [1] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Corneal erosion | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Eye inflammation | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Eye oedema | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Eye swelling | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Glare | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Lacrimation increased | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Ocular discomfort | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Retinal degeneration | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Visual acuity reduced | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Renal and urinary disorders | 18(21.177) | [26] | 3(3.529) | [3] | 3(3.529) | [3] | 0(0.000) | [0] | 12(14.118) | [13] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] |
| Urinary incontinence | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 5(5.882) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |

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|---|-------------------|-------------|-----------------|------------|-----------------|------------|-----------------|------------|----------|----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|------------|
| Dysuria | 6(7.059) | [6] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Haematuria | 5(5.882) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Micturition disorder | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Pollakiuria | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Neurogenic bladder | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | |
| Urinary retention | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Calculus bladder | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Enuresis | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Glycosuria | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Hypertonic bladder | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Micturition urgency | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Oliguria | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Renal failure acute | 1(1.177) | [1] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Renal tubular necrosis | 1(1.177) | [1] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Psychiatric disorders | 14(16.471) | [17] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1 | 6 | (18.824) | [22] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Insomnia | 7(8.235) | [9] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 7(8.235) | [7] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Depression | 4(4.706) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 6 | (7.059) | [7] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Mood altered | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Psychotic disorder | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Anxiety disorder | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Depressed mood | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1 | (1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Personality change | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Personality disorder | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Sleep disorder | 1(1.177) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Injury, poisoning and procedural complications | 16(18.824) | [22] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 7 | (8.235) | [8] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Excoriation | 4(4.706) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Ear abrasion | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |
| Procedural pain | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | |

| | | | | | | | | | | | | | | | | |
|---|-----------------|-------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|
| Contusion | 1(1.177) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Laceration | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Rib fracture | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Concussion | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Femur fracture | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hand fracture | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hip fracture | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Joint dislocation | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Post procedural oedema | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Radiation skin injury | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Skin injury | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Subdural haemorrhage | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Vascular disorders | 8(9.412) | [9] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 4(4.706) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hypotension | 4(4.706) | [5] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Flushing | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hypertension | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Shock | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Thrombosis | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Ear and labyrinth disorders | 7(8.235) | [12] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 4(4.706) | [6] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Tinnitus | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Ear pain | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Otorrhoea | 2(2.353) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Deafness | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Auricular swelling | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Ear discomfort | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Reproductive system and breast disorders | 5(5.882) | [6] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Vaginal haemorrhage | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Galactorrhoea | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |

| | | | | | | | | | | | | | | | | |
|--|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|-----------------|------------|
| Genital discharge | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Menopausal symptoms | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Menorrhagia | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Perineal pain | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Vulvovaginal swelling | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Immune system disorders | 1(1.177) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 4(4.706) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hypersensitivity | 1(1.177) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 4(4.706) | [4] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hepatobiliary disorders | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 4(4.706) | [5] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] |
| Hepatic steatosis | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 2(2.353) | [2] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hepatic cirrhosis | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hepatitis | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Hepatitis acute | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 1(1.177) | [1] | 1(1.177) | [1] | 0(0.000) | [0] |
| Cardiac disorders | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Arrhythmia | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Bradycardia | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Tachycardia | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Ventricular dysfunction | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Endocrine disorders | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 3(3.529) | [3] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Cushing's syndrome | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Cushingoid | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Thyroid mass | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |
| Uterine leiomyoma | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] | 1(1.177) | [1] | 0(0.000) | [0] | 0(0.000) | [0] | 0(0.000) | [0] |

Dictionary: MedDRA v16.0

◆ overlapping count