**Table 2.** Endpoints assessed in clinical trials on pediatric urinary tract infection compared with the FDA 2015 and EMA 2012 guidance

|  |  |  |  |
| --- | --- | --- | --- |
| **Endpoints** | **FDA 13** | **EMA 14** | **Number of studies using the criteria (%) n=40** |
| **Clinical Outcomes** |  |  | 38 (95) |
| Clinical cure/improvement | Yes | Yes | 15 (38) |
| Clinical failure/relapse/recurrence | Yes | No | 13 (33) |
| Resolution of signs-symptoms | Yes | Yes | 35 (88) |
| Compliance/Change of antibiotic | No | No | 9 (23) |
| Severity of diseasea | No | No | 4 (10) |
| **Laboratory Outcomes** |  |  | 23 (58) |
| Laboratory cure/improvement | No | No | 3 (8) |
| Normalization of inflammatory markers (WBC, CRP, ESR, PCT) | No | No | 9 (23) |
| **Microbiological Outcomes** |  |  | 37 (93) |
| Microbiological cure | Yes | Yes | 20 (50) |
| Microbiological failure/relapse/recurrence | Yes | Yes | 21 (53) |
| Urinalysis/Urine dipstick | No | No | 13 (33) |
| Urine culture | Yes | Yes | 36 (90) |
| Blood cultures | No | No | 3 (8) |
| **Radiological Outcomes** |  |  | 16 (40) |
| US | No | No | 3 (8) |
| DMSA (development of scars) | No | No | 13 (33) |
| Otherb |  |  | 6 (15) |

Abbreviations: FDA, Food Drug Administration; EMA, European Medicines Agency; WBC, white blood cells; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; PCT, procalcitonin; DMSA, Dimercaptosuccinic Acid Scintigraphy; US, ultrasonography

a Defined by possible complications (renal abscess, sepsis), hospitalization stay, rehospitalization rate, admission to ICU or mortality

b Adherence to prophylaxis after treatment (n=1), 27 patient’s interviews (n=3), 33, 34, 37 and overall costs (n=2). 34, 45