TABLE 4: Methods for starting dose selection in pediatric oncology studies in response to written requests initiated since 2001.

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| --- | --- | --- | --- |
|  | Rationale | Solid Tumor (N=23) | Hematological Malignancy (N=14) |
| Empirical Approach | Equivalent to body size adjusted adult dose | 1 | 8 |
| ~80% of body size adjusted adult dose | 13 | 1 |
| 50 or 70% of adult MTD or RP2D | 5 | 2 |
| PK Modeling and Simulation | Allometric scaling, Population PK modeling and simulation | 4 | 3 |