**Complexity is defined on the following aspects**

1. Study design and therapeutic Area (oncology, neuroscience is generally not low complexity unless it is just a simple ADME trial)
2. Total number of endpoints, variables to be derived, complexity of the derivation
3. Total number of outputs (incl. datasets and reports)
4. If the repeats are in the range of 15% of the total no. of outputs then the complexity is high ; if in the range of 15% to 30% of the total no. of outputs then the complexity is medium; if >30% then it is low (but this is still subject to volume and duration of delivery)
5. Duration of delivery
6. Pooling is generally considered complex due to the volume of the data.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Complexity | No. of endpoints | Datasets | TLFs | SDTM datasets | In-text tables | Repeats | Duration of delivery |
| Low/ Simple | <=4 | Simple 0 to 15 | Simple 75 to 100 | Simple 10 to 20 | Simple 0 to 10 | >30% | An year |
| Medium/ Standard | 4 to 8 | Medium 15 to 25 | Medium 100 to 150 | Medium 20 to 30 | Medium 10 to 20 | 15% to 30% | 6- 8 months |
| Complex | >8 | Complex 0 to 30 | Complex 150 to 175 | Complex 30 to 40 | Complex 20 to 30 | <=15% | Too soon <=6 months |

*The complexity is generally a combination of all the above and cannot just be determined by a standalone grid*