**TOGA Teletrials feasibility checklist**

Version 1.0 dated 15-Sep-2022

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| **Trial Name** |  |
| **Study Chair** |  |
| **Date checklist completed** |  |
| **Checklist completed by** |  |

|  |  |
| --- | --- |
| **Study treatment administration** |  |
| How is the study treatment administered to the patient? |  |
| What are the study treatment storage requirements? |  |
| Can the study treatment be delivered to the patient directly? |  |
| Does the study treatment require qualified and trained staff for drug administration/dispensing? |  |
| Does the study treatment require a clinical trial pharmacy or facilities for storage? |  |
| Does the study treatment require compounding and are the timeframes of expiry/storage requirements of compounded drug feasible for (secondary) sites that need to outsource their compounding/ or obtain compounded drug from the primary site? |  |
| Will there be extra costs involved in obtaining, shipping, storing and dispensing study treatments, and can the budget accommodate these? |  |
| What are the IMP accountability requirements, including drug expiry and destruction, and can this be managed at secondary sites? |  |
| **Trial outcome measures** |  |
| What are the key assessments that contribute to trial outcomes? |  |
| Can these assessments be adequately delegated to staff and providers at secondary sites, or performed remotely by phone/email/etc? |  |
| Who will be responsible for interpreting these results? |  |
| If remote/secondary assessments are not feasible, can central providers be set up, with patients travelling to the central provider for these tests only? Is this frequency of travel still amenable to recruitment from secondary sites? Are there any budgetary impacts?  |  |
| Does the secondary site have sufficient and qualified staff to enter data in the CRF, and can the budget accommodate database support for these additional users? |  |
| **Trial safety measures** |  |
| Are there any study-specific considerations regarding adverse event identification, reporting or follow-up that make the study unsuitable for teletrials? |  |
| **Trial monitoring** |  |
| Are there any study-specific considerations that will affect whether secondary sites can be adequately monitored using remote monitoring? |  |
| **Correlative studies** |  |
| Are the correlative studies amenable to teletrials? |  |
| Are secondary sites anticipated to have the required trained staff and equipment to collect/process/store samples, and can the budget accommodate transport costs from secondary sites to either a primary site or central laboratory? |  |
| If samples need to be processed by a third party or primary site, does the budget have adequate funds for this process and necessary shipping? |  |
| **PROMS** |  |
| How are the PROMS delivered (ePROMs or paper)? |  |
| Do they need to align to study visits at either the secondary or primary site? |  |
| **Other** |  |
| Are there any other known factors that need to be taken into consideration when assessing this trial for teletrials suitability? |  |