Instructions:

* There should be one Source Data Plan per site.
* There should only be one source defined at any time for any data point (e.g Inclusion/Exclusion Criteria should be split up into different rows and one source code recorded for each criteria)
* The source is the first place a piece of information is documented. Where there may be more than one source, chose a primary source which is the most reliable place and note any additional possible sources in the comments (e.g. where adverse events are usually recorded directly in the electronic medical notes for a trial but may also be recorded in a participant diary state ‘EMR’ for source but add ‘May also be PTD if event is patient reported’ in comments).
* For electronic source data (e.g. electronic medical records), list specific location within the electronic system for each data point (e.g. TRAK Clinical notes or Clinical Portal laboratory results).
* If there is any change in location of source data or documents throughout the trial, the PI or designee is responsible for updating the source data plan and providing a copy for the trial master file. Previous versions of the form should be superseded and retained in the ISF.
* The Source Data Plan must be completed prior to SATO.

\* In some cases study data may not be recorded in a source document but is instead recorded directly into the CRF. It will be documented in the study protocol and/or Source Data Plan that the CRF will act as the source for the specified study data points.

| **Data point**  List essential data required by the protocol | **Source**  This is where the data point is first documented.  Use source codes stated above. | **Location(s) at Site**  Specify where Source data may be found, please be specific where possible (e.g specify which file and where it is held, section of paper medical record or name of electronic medical record system) | **Comments/Additional Information**  It is expected that direct access to all source documents will be given to the monitor. Where a photocopy of paper source or a print out of EMR will be provided please make this clear. All copies must be verified as true copies. |
| --- | --- | --- | --- |
| Informed consent |  |  |  |
| Informed consent discussion |  |  |  |
| Demographics |  |  |  |
| Inclusion criteria assessments (please list): |  |  |  |
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|  |  |  |  |
| Exclusion criteria assessments (please list): |  |  |  |
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| Confirmation of eligibility |  |  |  |
| Pregnancy test result |  |  |  |
| Randomised treatment/number |  |  |  |
| Data required for minimisation/stratification at randomisation (please list): |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Medical history |  |  |  |
| Initial diagnosis |  |  |  |
| Physical exam |  |  |  |
| Height and weight |  |  |  |
| Vital Signs |  |  |  |
| CT/MRI/imaging (please specify) |  |  |  |
| Laboratory results (please specify) |  |  |  |
| Other study specific test results (please list) |  |  |  |
|  |  |  |  |
| IMP administration |  |  |  |
| IMP compliance |  |  |  |
| Concomitant medication |  |  |  |
| Adverse event – diagnosis/description of event |  |  |  |
| Adverse event - assessment (seriousness, causality, expectedness, severity) of event |  |  |  |
| Patient reported outcomes (please specify) |  |  |  |
| Rating scales/clinician assessment (Please specify) |  |  |  |
| Other endpoint data (if not listed above) |  |  |  |
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| **I confirm that this is a complete and accurate description of source data at this site and this information has been communicated to all site staff members. I agree that Sponsor delegated staff (e.g. Monitor) will be granted direct access to all source data.** | | |
| Completed By (Print Name and Study Role): | Signature: | Date Signed: |
| PI Name: | PI Signature: | Date Signed: |