**Box 1**.Definition of Terms.

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| Patient-Reported Outcome (PRO) | A health status report that comes directly from the patient[[7](#_ENREF_7)] |
| Health-Related Quality of Life (HRQL) | The effect of a disease and its treatment on an individuals physical, emotional and social well-being[[4](#_ENREF_4)] |
| In-Trial Activity | Activity spanning trial recruitment, data collection and data inputting |
| Concerning PRO Data | PRO data that raises concern for the wellbeing of the trial participant |
| Proxy PRO Assessment | Where an individual with a comprehensive knowledge of the trial participant is asked to complete the PRO on their behalf |