Title	MDS-UPDRS Translation Program for non-English official versions
Study Type	This is an observational study
Study Groups/Sites	10-15 non-English language groups with multiple sites within each language sphere.
Study Period	Two years: From the posting time of the program on MDS website, 8 months will be allocated for groups to sign up for the program. From the time a group signs up for the program, it will be given 12 months to complete the translation/back translation, cognitive testing, and validation phases; data analysis, feedback to program teams and finalization of reports will take place within 3 months of full data set submission by the core analytic team. The last four months will be used to finalize data analysis and reports to groups and MDS.
Study Population	Parkinson's disease patients whose native language is not English.
Primary Study Objective	To validate translations of the MDS-UPDRS
Study Design	Immediately after budget approval, CG Goetz, BC Tilley and GS Stebbins will prepare an announcement to be placed on the MDS website that the program is operative. An announcement at the Chicago MDS meeting will also publicize this program. Requirements for participation: o Local translation/back translation program will include two teams (translators and back translators) that operate under one director, but otherwise are independent for this phase of the program. o For each team, at least one person who is fluent in English and the native language and is a movement disorder specialist is required. Other specialists (professional translator, linguist, cultural expert etc are optional). An added credential of merit will be some designation from a local neurological organization that officially recognizes this translation program. o The proposed list of these two teams and the raters who will participate in the validation phase will be submitted to C Goetz who will obtain approval from the UPDRS Steering Committee before initiation of the program. o The Director for each language group will agree on behalf of the team to publication guidelines outlining that the investigators will have the responsibility to summarize their findings and submit them to the MDS. They will be encouraged to submit them for peer-review publication and will determine authorship independently of the UPDRS Steering Committee or the MDS. They will agree to acknowledge the MDS Task Force and list the members of the UPDRS Committee along with other people who participated in the program. C Goetz will have final approval of that list of acknowledgments Phase I: Translation and back translation o The translation and back translation will be submitted to C Goetz, who will identify an independent person from the movement disorder community of that country to review the translation and back translation. The independent person will submit a report to C Goetz. o The MDS-UPDRS Steering Committee will review the original submission and the critique of this local expert. Based on this review, revisions will be requested or the

	documents will be approved for Cognitive Testing. Phase II: Cognitive Testing o Provisionally approved translations will be returned to the local team with the request that a subset of potentially culturally sensitive or complex items undergo cognitive testing in a set of PD patients (approximately 10 PD patients). o Questions will be asked to the patient and examiner after each targeted item to assess patient and examiner understanding and comfort, using a guide (in English) prepared by a cognitive specialist (Nancy LaPelle). Before use, the guide will need to be translated by the team conducting the translation. o After review of the cognitive testing results using an analysis guide prepared by Dr. LaPelle, the translation team may identify problem areas. In the event that major issues are identified, further forward and back translations of some individual items may be needed along with further testing of those portions of the instrument. Whether a new translation is needed or there are minor issues, a response from the translation team (in English) to Dr. Goetz describing results of the cognitive testing will be reviewed by the Steering Committee for provisional approval of the translation that will now be fully tested (Phase III) Phase III: Large-scale validation testing. o Each translation team will administer the MDS-UPDRS to **350 PD patients** for a single visit. These patients should be native speakers of the language being tested. The patient sample should include samples from different ages, genders, severities of PD and educational levels. o Data entry and analysis. Sites will be encouraged to enter data directly onto a website developed for this program as part of the infrastructural cost. Statisticians in this program will provide the factor analysis and differential item function (DIF) scores. Other analyses that individual groups from each country wish to conduct can be handled by the team for each country and are not part of this program. Questions regarding individual sub-analyses and access to data will be directed to Dr. Goetz. o Primary outcome for designation of approval: confirmatory factor analysis will be run against the established English version factor structure by each section. Potentially, Differential Item Function will be run on items (both uniform and non-uniform DIF) by gender, race, disease severity, education and age. **To be designated as an official translation, CFI of the final model for each section of MDS-UPDRS must be $\geq$ 0.9 relative to the English version**.
Sample Size	There will be 350 subjects from each translation program spread among several sites. This calculation is based on the need for 5 subjects per item of the questionnaire in order to perform the statistical tasks needed to validate the instrument. There are 65 items on the MDS-UPDRS.
Inclusion Criteria	Patients with Parkinson's disease fluent in the native language of the site
Exclusion Criteria	Patients cannot be included if they do not have Parkinson's disease. Further, they cannot be included if the language translation being tested is not the native language of the patient.
Study Intervention	none
Primary Outcome Measure	The MDS-UPDRS factor scores and CFI of the final model for each section of the MDS-UPDRS

Statistical Analysis	A confirmatory factor analysis will be run against the established English-version factor structure, by section. Differential item functioning (DIF) will be run on all items (both uniform and non-uniform DIF) by gender, race, education and age group. This will be done by the site or by South Carolina depending on the data entry method used (i.e. website)