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RE: Document of Certification for the Japan (Japanese) Translation of the SF-36v2[®] Health Survey (Standard) Paper-Pencil Format

To whom it may concern:

With this document of attestation, OptumInsight Life Sciences, Inc. ("Optum") certifies that the Japan (Japanese) SF-36v2[®] Health Survey (Standard) Paper-Pencil Format (PPF) is appropriately reflective of and equivalent in content, format and intent of the original English version of the questionnaire. Optum further certifies that the translation of the SF-36v2[®] Health Survey (Standard) PPF was based on the SF-36v1[®] Health Survey (Standard) Health Survey PPF that underwent the standard cross-cultural adaptation methodology for linguistic validation as described below:

- Multiple independent forward translations by native Japanese-speakers
- Reconciliation of the translations into one form
- Back translation of the reconciled forward translation into English to check for conceptual equivalence
- Developer review of the finalized back translation evaluation report
- Qualitative debriefing tests with a small number of native Japanese-speakers in Japan
- Final formatting and proofreading of translation

This translation development was conducted in 1992 and last updated in 2004 as part of the IQOLA Project. Further details of the IQOLA translation process and its application in Japan can be found in the following peer-reviewed articles:

Bullinger M, Alonso J, Apolone G, Leplège A, Sullivan M, Wood-Dauphinee S, et al. Translating health status questionnaires and evaluating their quality: The International Quality of Life Assessment Project approach. *J Clin Epidemiol* 1998; 51:913-923.

Fukuhara S, Bito S, Green J, Hsiao A, Kurokawa K. Translation, adaptation, and validation of the SF-36 Health Survey for use in Japan. *J Clin Epidemiol* 1998; 51:1037-44.

Fukuhara S, Ware JE, Kosinski M, Wada S, Gandek B. Psychometric and clinical tests of validity of the Japanese SF-36 Health Survey. *J Clin Epidemiol* 1998; 51:1045-53.

The Japan (Japanese) SF-36v2[®] Health Survey translation was developed by reviewing the SF-36v1[®] Health Survey translation and making necessary wording revisions to develop the SF-36v2[®] Health Survey form. A team of bilingual researchers, whose native language is Japanese, led by Dr. Fukuhara, conducted the revision process.

Sincerely,

DocuSigned by:

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Angie Lee
Manager, Linguistic Solutions,
Patient Insights