

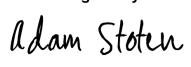


Clinical Outcomes

## **Proposal: Translation and Linguistic Validation of the OHS into Polish for Poland.**

10 September 2020  
Valid 90 days

CONFIDENTIAL: Translation and Linguistic Validation of the OHS into Polish for Poland

Proposal for:	Prepared by:
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<p><b>This Proposal is made subject to our Standard Terms and Conditions attached and if you accept this Proposal by signing below the contract between us will be formed for the supply of Services and that contract will be subject to our Standard Terms and Conditions. If there is any conflict or inconsistency between this Proposal and our Standard Terms and Conditions, the Proposal will prevail.</b></p> <p><b>To accept this Proposal please send back a countersigned copy to indicate your agreement to these terms.</b></p> <p><b>This Proposal is valid for 90 days.</b></p>	
<b>ON BEHALF OF LIMACORPORATE:</b>	<b>ON BEHALF OF OXFORD UNIVERSITY INNOVATION LIMITED:</b>
NAME: Luca Vozzi	NAME: Adam Stoten
SIGNATURE: DocuSigned by: 	SIGNATURE: DocuSigned by: 
DATE: 2EA5F484ABD64F0... 9/10/2020   11:01 CEST	DATE: 12 October 2020   08:52 BST

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## 1 Study Requirements

LimaCorporate has requested that the Clinical Outcomes team at Oxford University Innovation Ltd. prepare a proposal for the translation and linguistic validation of the OHS Questionnaire, a clinical outcome assessment (COA) which copyright is managed by OUI. This proposal will be based on the source files *OHS English*, (owned by OUI) and the translation is into Polish (Poland).

## 2 Study Methodology

### 2.1 *Translation and linguistic validation of the OHS*

The linguistic validation methodology that will be employed for the OHS includes the following steps, which conform to the requirements of both the OHS developers and copyright holders and the FDA and EMA regulatory agencies.

Translation and linguistic validation methodology will be employed for the following languages:

#### *Standard TLV including developer review*

- Polish for Poland

Concept Elaboration	An existing concept elaboration report will be used for the OHS. The concept elaboration report clarifies the intended meaning of each item, provides acceptable alternatives for translations if direct translations are not possible, and will be used as a guidance document throughout the study.
Two Forward Translations	The OHS will be translated twice from English into the target language. The translations will be conducted by professional medical translators (native target language speakers).
Forward Translation Reconciliation	The in-country investigator will reconcile the forward translations to produce a single translation of the highest quality which is both linguistically accurate and culturally relevant to the target country.
Two Back Translations	The reconciled translation will be back translated into English by two professional medical translators (native English speakers) who have not seen the original source text.
Back Translation Review	The project manager will review the back translations against the source text and work with the in-country investigator to resolve any discrepancies in meaning between the translations.
Developer Review	The completed back translation review report will be sent to the developer to obtain their approval of all the decisions made up to that point in the translation study.
Independent Proofreading	The translation at this stage will be proofread by a medical translator (native target language speaker) who hasn't been involved in the study to date, to ensure complete accuracy and zero errors prior to the cognitive debriefing interviews.
Cognitive Debriefing Interviews	The in-country investigator will recruit and ask 5 to participate in an <u>over-the-phone or online</u> interview: OHS – 5 adults awaiting a total hip replacement (THR)

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	or patients who have had a THR in the past 3 months; Each person will firstly complete the OKS and OHS. They will then be taken through the COA sentence by sentence and asked to comment on whether they understood the instructions, questions, and response options, comment on whether any words or phrases were difficult to understand and if so to suggest alternative wording and finally, to describe in their own words (paraphrase) what the wording in the OKS and OHS means to them. Any issues raised by the participants and any inaccurate paraphrasing will be entered into a pilot testing report, this will be reviewed by the project manager and discussed with the in-country investigator to ensure that the final wording is fully acceptable to the patient population the OKS and OHS is designed for.
Developer Review	The completed Cognitive debriefing review report will be sent to the developer to obtain their approval of all the decisions made up to that point in the translation study.
Professional Formatting	If any changes are made as a result of the cognitive debriefing interviews, the translation will be proofread for a second time to ensure 100% accuracy. Following this step or if no changes were made, the translated text will be reviewed and formatted, to ensure the translated text is perfectly formatted and the correct fonts for the target language have been used.

**3 Deliverables**

Oxford University Innovation Ltd. will provide LimaCorporate with the following:

- A weekly project status report
- Final formatted translations in MS Word
- A certification letter outlining the translation methodology that was undertaken

## 4 Timeline and Budget

For the purposes of this proposal, one week is based on 5 working days and excludes any public holidays in England.

The following table outlines the timeline for completion of the translation and linguistic validation process:

Language	Country	Methodology	Timeline*	Budget
Polish	Poland	TLV	9 weeks	£7,800.00
<b>TOTAL TRANSLATION BUDGET</b>				<b>£7,800.00</b>

TLV: Translation and Linguistic Validation

*\*Note: due to the current world situation as consequence of Covid-19 pandemic, OUI is unable to guarantee any timelines. OUI reserves the right of extending the turnaround time shall there be recruiting difficulties or limited linguists' availability. OUI will inform the client in due course regarding any development.*

Timeline and budget assumptions:

- The timeline **does not** include the developer's time in reviewing the interview adaptation, concept elaboration report or the back-translation review report. Oxford University Innovation Ltd. cannot be held responsible for delays in the project due to the OKS and OHS developer.

### Invoices:

One invoice will be raised for this project, 100% on completion.

## 5 Appendices

### 5.1 Study Team

#### 5.1.1 The Clinical Outcomes team at Oxford University Innovation Ltd.

Oxford University Innovation Ltd. (OUI) is the technology transfer company for the University of Oxford. Within OUI is the Clinical Outcomes team dedicated to supporting the use of Clinical Outcomes Assessments (COA), the vast majority being Patient Reported Outcomes (PRO) measures. The Clinical Outcomes team is involved with all aspects of COA management including translation and linguistic validation and eCOA activity, which we are thought leaders in. The Clinical Outcomes team manage a rapidly growing portfolio of high quality COA measures and a library of over 250 translations of the instruments we manage. The Clinical Outcomes team is headed by Dr. David Churchman who has over 10 years' experience in COAs and is an associate of the Health Services Research Unit, Nuffield Department of Population Health at the University of Oxford, and an active member of ISOQOL and ISPOR.

#### 5.1.2 Study Management

##### **Darren Clayson, MSc – Project Manager**

Darren is a psychologist and consultant outcomes researcher who has been working closely with Oxford University Innovation Ltd for approaching 10 years. He was also the founder and director of PharmaQuest Ltd., a medical translation company specialising in translation and linguistic validation of COAs until its sale in 2013. Darren has overseen several hundred linguistic validation projects and now works for a number of agencies providing expert advice as well as acting as a project manager and a UK English in-country investigator.

#### 5.1.2 In-Country Investigators

In-country investigators are resident in the target country, native speakers of the target language, fluent in English and have relevant backgrounds, including outcomes research/health/linguistics/medicine/psychology. They have experience of working on translation and linguistic validation projects of COAs for the pharmaceutical industry.

#### 5.1.3 Translators

##### **Forward Translators & Proofreaders**

The forward translators and proofreaders are medical translators with at least 3 years' translation experience and a qualification in translation or languages. They are native speakers of the target language and fluent in English.

##### **Back Translators**

The back translators are medical translators with at least 3 years' translation experience and a qualification in translation or languages. They are native speakers of English and fluent in the target language.



## 5.2 *Translation Related Publications*

**Clayson D, Verjee-Lorenz A, Two R, Gerber R, Beaudreuil J.** (2011). Translation and linguistic validation – Methodological implications when the source measure is not English. *Value in Health* 14(3): A154.

**Clayson D, Verjee-Lorenz A, Miller F, Two R.** (2011). The role of the instrument developer in the translation of patient reported outcome measures. *Value in Health* 14(7): A432.

**Harrington R, Churchman D, Dawson J, Clayson D, Price A, Rees J.** (2012). Routine electronic patient reported outcome (ePRO) data collection in an orthopaedic outpatient clinic – Methods used to ensure proper migration of the PRO measure and benefits to the care pathway. *Value in Health* 15 (4): A43.

Simpson H, Two R, Verjee-Lorenz A, **Clayson D.** (2012). Identification of Culturally Bound Terms in Patient Reported Outcome Measures. *Value in Health* 15(7): A492.

Two R, Verjee-Lorenz A, **Clayson D**, Dalal M, Grotzinger K, Younossi ZM. (2010). A Methodology for Successfully Producing Global Translations of Patient Reported Outcome Measures for Use in Multiple Countries. *Value in Health* 13(1): 128-131.

Two R, Verjee-Lorenz A, **Clayson D**, Dalal M, Grotzinger K, Younossi ZM. (2010). Response to the Letter from Ms. Tamzin Furtado. *Value in Health* 13(4): 508-508.

Verjee-Lorenz A, **Clayson D**, Two R, Giovanaz M. (2010). Concept Elaboration—an essential stage in the translation of PRO measures. *Value in Health* 13(7): A338.

Verjee-Lorenz A, **Clayson D**, Two R. (2011). Pilot Testing Translations of PRO Measures with Sensitive Populations. *Value in Health* 14(3): A153.

Verjee-Lorenz A, Two R, **Clayson D**, Miller F. (2011). Comparison of reconciliation and review methodologies for the translation of patient reported outcome (PRO) measures. *Value in Health* 14(7): A432.

## STANDARD TERMS AND CONDITIONS

**These Conditions apply to and govern the supply of services by Oxford University Innovation Limited whose registered office is at University Offices, Wellington Square, Oxford OX1 2JD (“OUI”).**

### 1. Definitions and Interpretation

1.1 In these Conditions the following words have the following meanings:

the Agreement	means an agreement for the purchase of the Services by the Company from OUI;
the Company	means the company or entity defined on page 2 of the Proposal;
the Company Representative	means the individual named in the Proposal;
the Conditions	means these terms and conditions;
the Contract Period	means the period and Timeline set out in section 4 of the Proposal;
the Contract Price	means the price for the Services set out in section 4 of the Proposal
the Deliverables	means the deliverables identified in section 3 of the Proposal;
the Proposal	means a written proposal issued by OUI specifying the Services to be performed and the cost of the Services and incorporating these terms by reference;
the Questionnaire	means the questionnaire as identified in Section 1, Study Requirements of the Proposal; and
the Services	means the services to be performed by OUI as set out in Section 2 (Methodology) and 3 (Deliverables) of the Proposal.

- 1.2 OUI and Company are together referred to as “Parties” and individually as “Party”.
- 1.3 The headings in this Agreement shall not affect the interpretation of this Agreement. The singular includes the plural and vice versa and one gender includes the others. Use of the words “includes” and “including” shall be construed as being without limitation. References to statutes and regulations shall be to these as they may be amended or revised from time to time.

## **2. Services**

- 2.1 In consideration of the Contract Price OUI shall provide the Services to the Company, on a non-exclusive basis and make available the Deliverables to the Company.
- 2.2 OUI will use reasonable skill and care in carrying out the Services.
- 2.3 OUI will keep Company Representative informed of progress made on the Services and provide updates on reasonable request by the Company from time to time.
- 2.4 OUI will use all reasonable endeavours to complete the Services within the Services Period. However, OUI shall have no liability for failing to do so and time shall not be regarded as being of the essence. OUI will notify the Company of any anticipated delays in the Services and use all reasonable endeavours to minimise the delays.

## **3. Company Materials**

- 3.1 The commencement and completion of the Services is subject to the supply by Company to OUI of any information or materials that OUI reasonably requires in order to properly carry out the Services.

## **4. Contract Price**

- 4.1 Unless the Proposal states otherwise and subject to OUI providing a VAT invoice, the Contract Price shall be paid in full on delivery of the final translation. All prices are deemed to be expressed exclusive of VAT.
- 4.2 Interest may be charged by OUI at 2% per month on all overdue payments from the date that payment was due until payment is received by OUI.

## **5. Intellectual Property**

- 5.1 This Agreement is not intended to result in the transfer or licence of any intellectual property rights by either Party to the other.
- 5.2 OUI shall have no liability for verifying, procuring or maintaining any rights that may be desirable or required for the Company to use the Questionnaire or for OUI to carry out the Services, which shall be the sole responsibility of Company.

## **6. Confidentiality**

- 6.1 Each Party shall keep confidential and not disclose to any third party information that is marked confidential or apparent by its nature or the manner of its disclosure to be confidential that is received from (or on behalf of) the disclosing Party and will only use that confidential information for the performance of the Services or in connection with this Agreement or its purposes.



- 6.2 The obligations in clause 6.1 do not apply to information that was already known to the receiving Party; was received by the receiving Party from a third party without breaching a duty of confidentiality; is or becomes publicly known without the fault of the receiving party; is or has been independently developed by the receiving party's staff who did not have any access to any of the disclosing Party's Confidential Information; or is approved in writing for release by the disclosing Party. Nothing in this Agreement will prevent the recipient from disclosing information where it is required to do so by order of a court of competent jurisdiction or by law (including under the Freedom of Information Act 2000 (FOIA)).
- 6.3 The obligations of confidentiality in respect of any confidential information in clause 6 shall survive for five years from the date of initial disclosure of that Confidential Information.

## **7. Liability**

- 7.1 OUI accepts no responsibility for any errors, omissions or other defects in any information, instructions, specifications or materials provided by or on behalf of Company or any consequential errors, omissions or other defects in the Services or the Deliverables and any additional work or Services required to be carried out by OUI as a result shall be charged for accordingly.
- 7.2 On submission of the final language version(s) of the Questionnaire(s), the Company will have 30 days to raise any queries. Except as expressly stated otherwise in this Agreement, OUI excludes to the fullest extent permitted by law all warranties, conditions or terms, express or implied, statutory or otherwise, including (without limitation) as to the condition, performance, fitness for purpose or satisfactory quality of the Services or the Deliverables.
- 7.3 Without affecting the generality of clause 7.2, OUI give no implied or express warranty and make no representation that the Deliverables or any questionnaire on which they are based:
  - 7.3.1 will enable specific results to be obtained;
  - 7.3.2 meets a particular specification or is comprehensive within its field;
  - 7.3.3 is suitable for any particular, or the Company's specific, purposes;
  - 7.3.4 does not or will not infringe third party rights.
- 7.4 The Company will be responsible for obtaining any licence or permissions required from owner of copyright in any third party health outcomes questionnaire to be assessed or otherwise used by OUI for the purposes of the Services and OUI will have no liability in relation to any data obtained by the Company from any such questionnaire.
- 7.5 Subject to clause 7.6, the liability of either Party for any breach of this Agreement, for any negligence or arising in any other way out of the subject-matter of this Agreement, will not extend to loss of business, profit, revenue, contracts, opportunity, reputation or data (in each case whether direct or indirect), or to any indirect or consequential damages or losses even if they were within the Parties' contemplation at the date of this Agreement.

- 7.6 Subject to clause 7.6, the maximum liability of OUI to the Company under or in connection with this Agreement whether in contract, tort (including negligence) or otherwise shall not exceed in aggregate the total amount of the Contract Price and Expenses (excluding VAT or other similar taxes or duties) invoiced by OUI in respect of the Services up to the date of the event or circumstance giving rise to the relevant claim.
- 7.7 Nothing in this Agreement shall exclude or limit any liability of either Party for (a) fraud or wilful misconduct; and/or; (b) negligence causing personal injury or death.
- 7.8 Any action by either Party against the other relating to or arising out of the Services must be brought within one (1) year after the aggrieved Party became aware of (or should reasonably have become aware of) the cause of action, failing which the alleged wrongdoer will be discharged of any liability with respect to the claim.
- 7.9 The Company will not make any claim for damages against any individual employed or engaged by OUI or the University personally except in case of fraud or wilful misconduct.
- 7.10 The allocations of liability in this Agreement represent the agreed and negotiated understanding of the Parties and OUI's charges for the Services reflect such allocations.

## **8. Termination**

- 8.1 Either Party may terminate this Agreement immediately if (a) the other Party becomes insolvent or has proceedings commenced against it under insolvency law (including the appointment of an administrator or liquidator) that are not promptly dismissed and (b) if the other Party is in material breach of any term of the Agreement and where the breach is capable of being remedied, fails to remedy the breach after receiving a written notice that specifies the breach and the steps required to remedy it and a reasonable opportunity to remedy the breach.
- 8.2 If the Company cancels the Services at any point during the Contract Period, OUI will be entitled to charge the Company for the work completed as follows (for each language)

<b>Stage started</b>	<b>Percentage of Contract Price</b>
Project initiation	10%
Forward translation	20%
Forward translation reconciliation	30%
Back translation	40%
Back translation review	50%
Developer/client review	60%
Independent proofreading	70%
Pilot testing	100%

- 8.3 On termination of this Agreement for any reason, the Company shall immediately pay all outstanding sums to OUI without making any set-off, withholding or deduction.
- 8.4 Termination of this Agreement shall not affect the accrued rights and liabilities of the Parties and clauses 5, 6, 7, 8.3, 8.4 and 10 inclusive shall survive termination of this Agreement.

**9. Force Majeure**

If the performance of the Services by OUI is delayed, or prevented by any circumstances or conditions beyond OUI's control, OUI shall have the right at its option to: a) suspend further performance of the Services until such time as the cause of the delay shall no longer be present or; (b) be discharged from further performance of and liability under this Agreement and if OUI exercises such right Company shall pay that part of the Contract Price and Expenses which relate to the Services already performed.

**10. General**

- 10.1 Assignment** – The Company shall not assign or transfer or purport to assign or transfer any of its rights or obligations under this Agreement.
- 10.2 Announcements** - No public announcement or communication (save as may be required by law) concerning the transactions referred to in this Agreement shall be made or dispatched by either Party without the prior written consent of the other Party, not to be unreasonably withheld or delayed.
- 10.3 Use of Name** - Neither Party will use the name of the other, or, in the case of the Company, OUI and/or the University, in any marketing, advertising or promotion or to endorse any product or service unless the other Party gives or, in the case of OUI, procures the prior written consent of the other.
- 10.4 No Partnership** – Nothing in this Agreement creates, implies or evidences any partnership or joint venture between the Parties or the relationship of principal and agent. Neither Party shall be or hold itself out as being the agent or representative of the other.
- 10.5 Entire Agreement** - This Agreement constitutes the entire agreement between the Parties relating to the subject matter of this Agreement and supersedes all previous such agreements. The Company warrants that it has not relied on any representation made by or on behalf of OUI that is not expressly set out in this Agreement and waives all claims for breach of any warranty and all claims for any misrepresentation, (negligent or of any other kind, unless made by us fraudulently) in relation to any representation which is not specifically set out in this Agreement.
- 10.6 Variation** - No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of each of the Parties.
- 10.7 Waiver** - The failure to exercise or delay in exercising a right or remedy under this Agreement shall not constitute a waiver of the right or remedy or a waiver of any other rights or remedies and no single or partial exercise of any right or remedy under this Agreement shall prevent any further exercise of the right or remedy or the exercise of any other right or remedy.
- 10.8 Notices** – Notices under this Agreement may be validly served by each Party at the other Party's address given at the top of this Agreement, or such other address as either Party may in writing notify to the other for such purpose.
- 10.9 Third Party Rights** – Except as provided for the benefit of the employees and appointees of OUI and the University in clause 5.5 above, no third party is intended to benefit from any rights under this Agreement.
- 10.10 Governing Law** - English Law governs this Agreement and the Parties submit to the exclusive jurisdiction of the English courts for the resolution of any dispute which may arise out of or in connection with this Agreement