

Clinical Outcomes Project Number:	2973
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OXFORD UNIVERSITY INNOVATION LIMITED
LICENCE AGREEMENT FOR HEALTH OUTCOMES QUESTIONNAIRE

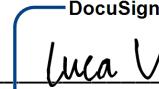
PARTIES:

(1) Lessor:	Oxford University Innovation Limited with a principal place of business situated at Buxton Court, 3 West Way, Oxford OX2 0SZ
(2) Licensee:	LimaCorporate SpA with a principal place of business at Via Nazionale 52, 33038 Villanova di San Daniele del Friuli, Udine, Italy

This agreement (the "Licence Agreement") comprises the Commercial Terms below and the General Terms and Conditions of Licence ("the General Terms") and expressions used in the Licence Agreement have the meaning set out in the Commercial Terms.

Commercial Terms:

Commencement Date	01/12/2020
Questionnaires	The health outcomes questionnaires titled: Oxford Hip Score
Authors	As detailed in the footer of the Questionnaire – or list Authors
Clinical Study	H-34
Intended Use	For a prospective, monocentric (1 site in PL), post-market, open-label, longitudinal cohort study. The aim of the study is to evaluate clinical, radiographic and PROMs of THA with Delta Revision Acetabular Cups from preoperative to 5-year follow-up.
Required Quantity	49 patients times 9 assessments = 441 uses
Required Translations	
Commissioned Translation	Polish for Poland, subject to separate agreement and fees
Term	Five years
Territory	Poland
Initial Licence Fee	441 times £2 = £882
Annual Licence Fee	
Translation Fee	
Contact details for Licensee	Name of Manager: Gloria Viti, Clinical Trial Lead Tel: +39/337 1532539 E-Mail: gloria.viti@limacorporate.com

Signed on behalf of Licensor:	Sign: _____  EEC309430C2E4A0... Adam Stoten coo Print Name and Job Title: 12 October 2020 08:54 BST Date:
Signed on behalf of Licensee:	Sign: _____  2EA5F48AABD64F0... Luca Vozzi VP Operations Print Name and Job Title: 9/10/2020 16:25 CEST Date:

GENERAL TERMS & CONDITIONS OF LICENCE

1. Interpretation

- 1.1 The Licensor and Licensee are together referred to as "Parties" and individually as "Party".
- 1.2 The headings in this Licence Agreement shall not affect the interpretation of this Licence 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.

2. Licence

- 2.1 The Licensor hereby grants to the Licensee a non-exclusive, non-transferable licence for the Term to make copies of the Questionnaire up to the Required Quantity and to use the copies of the Questionnaire for the Intended Use on the terms of this Licence Agreement. Where the Licensee's use of the Questionnaires is for a Clinical Study the licence granted is limited to use of the Questionnaire in the Clinical Study only.
- 2.2 The Licensee will not adapt or modify the Questionnaire in any way except as may be expressly authorised as part of the Intended Use. For the avoidance of doubt, the Licensee does not have the right to commercialise the Questionnaire in any manner.
- 2.3 The Licensee may only make additional copies over and above the Required Quantity; where the Licensee has first obtained the Licensor's permission to do so and paid a supplemental licence fee as specified by the Licensor, which will be commensurate with the Initial Licence Fee. Please submit any requests by email to healthoutcomes@innovation.ox.ac.uk. If the Licensee fails to comply with this clause, then (without affecting any of its other rights) the Licensor reserves the right to terminate the Licence Agreement for breach and accordingly the Licensee must destroy all data and copies of the Questionnaire that it has gathered or made.
- 2.4 The licence granted under clause 2.1 does not carry any right of sub-license except the limited right where the Intended Use relates to a Clinical Study and then the licence granted automatically includes a right to sub-license to: an Affiliate; the principal investigators and their teams; clinical study trial centres; CROs and CRAs; in each case provided that:
 - 2.4.1 the sub-licensee is directly involved with the performance of the Clinical Study,
 - 2.4.2 the sub-licensee is not a medic or clinician who has been previously debarred from practicing; and
 - 2.4.3 the identity of the proposed sub-licensee or the nature of its business is not likely to have a detrimental impact on the Licensor's reputation or that of the University of Oxford and the Licensor have the final decision in its absolute discretion in the case of any dispute regarding reputational matters.
- 2.5 Where an Initial Licence fee or an Annual Licence Fee is payable by the Licensee based on the volume of use of the Questionnaire during the Licence Term, the Licensee will provide to the Licensor a licence report within 30 days after the close of each twelve (12) month period beginning on the Commencement Date and each anniversary of the Commencement Date setting out details, by Questionnaire, of each client of the Licensee who has used each Questionnaire and the number of patients assessed by each client using each Questionnaire in the Licence Year.

3. Translations

- 3.1. The Licensee is only licensed to use translations included in the Required Translations and any Commissioned Translation. The Licensee will not use other translations except in accordance with clauses 3.2 and 3.3.
- 3.2. If the Licensee wishes to use a further translation of the Questionnaire that was not included in the Required Translations or the Commissioned Translation the Licensee should contact the Licenser with details of the translation the Licensee requires by email sent to healthoutcomes@innovation.ox.ac.uk. Following a request by a Licensee for a translation:
 - 3.2.1. the Licenser will inform the Licensee whether the translation is available and the fee charged by the Licenser for that translation. The Licensee may then place an order with the Licenser for the translation and the Licenser will supply that translation for the required fee as shown in the Licenser's prevailing list price for the translation as notified to Licensee [and that translation will be deemed to count towards the Required Quantity].
 - 3.2.2. if the required translation is not available the Licensee may request the Licenser to commission a translation at a price to be agreed between the parties at the time. Licensee shall pay 100% of any fees for the translation in advance if requested to do so by the Licenser.
- 3.3. Any Commissioned Translation will be produced strictly in accordance with the document: "Clinical Outcomes": Translation and Linguistic Validation Process" version June 2016, a copy of which is available on request by email sent to healthoutcomes@innovation.ox.ac.uk ("the TLV Process").
- 3.4. As between the Licensee and the Licenser, the copyright in any translations supplied by the Licenser to the Licensee under clause 3.2 shall belong solely to the Licenser.
- 3.5. The Licensee may not make or use any other translations of the Questionnaire that have not been supplied by the Licenser except in accordance with the following conditions:
 - 3.5.1. the Licensee has obtained the Licenser's written permission to do so;
 - 3.5.2. the translation is translated from the original parent language as specified by the Licenser (which will normally be in the English language);
 - 3.5.3. the translation must be strictly in accordance with the TLV Process;
 - 3.5.4. before putting the Questionnaire into use the Licensee must provide the Licenser with written confirmation of adherence of the translation to the TLV Process together with electronic (Microsoft Word or other format readily read by Microsoft Word) copies of the Questionnaire in final translated form;
 - 3.5.5. the Licensee may not deviate from the certified translation in the Licensee's use of the translation; and
 - 3.5.6. the Licensee will assign to the Licenser the copyright in the translation free of any third party claims.

4. Electronic Versions

- 4.1. The Licensee may not make or use on a hand held device or via a web based platform an

electronic version of the Questionnaire, an electronic Clinical Outcomes Assessment (an “eCOA”), except in accordance with the following conditions:

- 4.1.1. The Licensee must first obtain the Licenser’s written permission;
- 4.1.2. the eCOA must be created and implemented strictly in accordance with following Clinical Outcomes document: “Clinical Outcomes – Guidelines for the production of eCOA Measures” version June 2016 a copy of which is available on request by email sent to healthoutcomes@innovation.ox.ac.uk;
- 4.1.3. if the eCOA is web based then:
 - 4.1.3.1. the Licensee must enter into a supplemental licence agreement in the Licenser’s standard form, that covers additional commercial and legal matters that are specific to web based use of the Questionnaire; and
 - 4.1.3.2. all users of the eCOA shall be subject to a registration system that controls and monitors use in accordance with procedures approved by the Licenser.
- 4.1.4. the Licensee will assign to the Licenser the copyright in the eCOA version of the Questionnaire free of any third party claims.

5. Intellectual Property

- 5.1. The Licensee acknowledge that as between the Licensee and the Licenser, the Licenser owns the copyright in the Questionnaire and the Licensee agrees that the Licensee shall not obtain any right, title or interest in or to the copyright or other intellectual property rights in respect of the Questionnaire other than as expressly granted to the Licensee under the Licence Agreement.
- 5.2. The authors of the Questionnaire have asserted their moral rights (under Sections 77 to 89 of the Copyright Designs and Patents Act 1988 in the United Kingdom and equivalent rights in the rest of the world). The Licensee must procure the waiver and release of any and all moral rights in any translations that the Licensee procures.
- 5.3. The Licensee must accurately reproduce the copyright notice in every copy of the Questionnaire (including all translations) that the Licensee makes. The copyright notice must appear in the same place and as far as practicable in the same format as the notice placed by the Licenser on the document that the Licenser supplies to the Licensee under the Licence Agreement.
- 5.4. Where the Licensee has paid an Initial Licence Fee the Licenser makes no claim to the data generated using the Questionnaires or require further fees in relation to the Licensee’s use of that data. In all other cases the Licensee agrees that :
 - 5.4.1. they are only licensed to use data generated using the Questionnaire for non-commercial education, research and clinical patient care purposes as part of the Intended Use; and
 - 5.4.2. any commercial sale of the data or services using the data will require a further licence from us and payment of a licence fee.
- 5.5. All other copyright and intellectual property rights that may be generated in connection with

the Licence Agreement or the Licensee's use of the Questionnaires including in respect of any permitted translations or eCOAs that are created, shall belong solely to the Licensor, free of any third party claims. The Licensee shall enter into an assignment or other instrument as the Licensor may request (whether before or at any time after the end of the Licence Agreement) to enable the Licensor to obtain the full benefit of this clause.

6. Licence Fees

- 6.1. The Licensee will pay the Initial Licence Fee to the Licensor. All fees due are non-refundable and non-creditable and, where the Licensee has chosen to make payment after being invoiced, the Licensee will pay the sum due under the invoice no later than (45) forty-five days from the date of the invoice.
- 6.2. The Licensor reserves the right by giving the Licensee notice to suspend the Commencement Date, or if the Term has already started then to suspend the Licensee's continued use of the Questionnaires, if the Initial Licence Fee is not paid in full, without making any deduction, withholding or set-off, by the due date.
- 6.3. In the event that full payment of any amount due from the Licensee under the Licence Agreement is not made by any of the dates stipulated, the Licensor will be entitled to charge and the Licensee will pay interest on the amount unpaid at the rate of 1% per month. Such interest shall accrue on a daily basis from the date when payment was due until the date of actual payment of the overdue amount whether before or after judgment.

7. Warranties and Liability

- 7.1. The Questionnaires and associated material are provided on an 'as is' basis and the Licensee agree to use these at the Licensee's own risk. No representations, conditions, warranties or other terms of any kind are given in respect of the Questionnaires and any associated material, and all statutory warranties and conditions are excluded to the fullest extent permitted by law.
- 7.2. Without affecting the generality of clause 7.1, the Licensor give no implied or express warranty and make no representation that the Questionnaires or any part of them:
 - 7.2.1. will enable specific results to be obtained;
 - 7.2.2. meets a particular specification or is comprehensive within its field;
 - 7.2.3. is suitable for any particular, or the Licensee's specific, purposes;
 - 7.2.4. will not cause any loss damage or injury;
 - 7.2.5. that it is of satisfactory quality; or
 - 7.2.6. does not or will not infringe third party rights.
- 7.3. Except for death or personal injury caused by the Licensor's negligence or for fraud, the Licensor's liability under the Licence Agreement whether arising in contract, or tort (including negligence) or arising in any other way for any direct or indirect loss:
 - 7.3.1. shall be limited in aggregate to the total amount of the Initial Licence Fee and any supplemental fees received by the Licensor pursuant to clause 6.1; and
 - 7.3.2. excludes any liability for loss of profit, reputation, or business or opportunity

and for any indirect or consequential loss or damage, even if any of these types of loss or damage were foreseeable when the Licence Agreement was made.

- 7.4. The Licensee irrevocably undertakes not to make any claim against any employee, student, agent or appointee of the Licensor or of the University of Oxford, the Authors or the owners of the copyright in the Questionnaire, being a claim which seeks to enforce against any of them any liability whatsoever in connection with the Licence Agreement or its subject-matter.
- 7.5. The Licensee shall be responsible for all acts and omissions of the Licensee's permitted sub-licensees and the Licensee shall hold harmless and indemnify the Licensor, the University of Oxford and other funders or contributing parties of or to the copyright or other intellectual property rights relating to the Questionnaire and any other materials that are licensed to the Licensee under the Licence Agreement from and against any claim, liability, loss or damage that the Licensor or University of Oxford may suffer or incur arising out of any breach of the Licence Agreement or any negligent act or omission by the Licensee or the Licensee's permitted sub-licensees.

8. Confidentiality

- 8.1. Each party shall keep any commercial, technical and other information that is of a confidential nature (whether oral, written or recorded or disclosed in any other form) that may be disclosed to it by the other party in connection with the Licence Agreement confidential and not disclose it to any third party except:
 - 8.1.1. where the information is in or comes into the public domain other than as a result of any breach of this term;
 - 8.1.2. both parties may disclose the other party's information to professional advisers and (on a need to know basis) to Affiliates' employees and the employees of permitted sub-licensees; and
 - 8.1.3. we may disclose any information disclosed by you (excluding any Personal Data as defined in the Data Protection Act 2018) including details of any Clinical Study to the University or to any other funders, owners or contributing parties of or to the copyright or other intellectual property rights relating to the Questionnaire in order for those institutions to make submissions to the Research Excellence Framework.
- 8.2. Nothing in these Licence Terms will prevent a party from disclosing any information that may be disclosed to it by the other party where it is specifically required to disclose that information pursuant to applicable law (including the Freedom of Information Act 2000), or required or requested to be disclosed by a governmental authority or by order of any court of competent jurisdiction provided that: (a) in the case of a disclosure under the Freedom of Information Act 2000, none of the exemptions to that Act applies to the information; and (b) that party shall to the extent legally permitted, notify the other party of any such disclosure requirement or request as soon as practicable.

9. Duration and Termination

- 9.1. The Licence Agreement will commence on the Commencement Date and continue for the Term unless terminated at an earlier date in accordance with this clause 9.
- 9.2. The Licensor may terminate the Licence Agreement forthwith by written notice if:
 - 9.2.1. the Licensee is in breach of the Licence Agreement and, if the breach is

- capable of remedy, the Licensee fails to remedy the breach within 21 days of being requested in writing by the Licenser to do so;
- 9.2.2. if the Licensee has a petition presented for the Licensee's winding-up, or the Licensee passes a resolution for voluntary winding-up otherwise than for the purposes of a bona fide amalgamation or reconstruction, or the Licensee compounds with its creditors, or has a receiver or administrative receiver appointed of all or any part of its assets, or enter into any arrangements with creditors, or take or suffer any similar action in consequence of debts.
- 9.3. On termination of the Licence Agreement for any reason, the Licensee shall immediately pay all outstanding sums owed to the Licenser, cease using the Questionnaire (including all translations and eCOA versions) and all associated materials (such as user manuals) that the Licenser has provided to the Licensee and destroy or cause to be destroyed all stocks and electronic copies of the Questionnaire that may be in the Licensee's possession or control and if the Licenser asks the Licensee to, then the Licensee must certify to the Licenser that the destruction has taken place.
- 9.4. Termination of the Licence Agreement shall not affect either Party's accrued rights and liabilities. Clauses 1, 5, 7, 8, 9.3, 9.4 and 10 shall survive the expiry or termination of the Licence Agreement.

10. General

- 10.1. **Assignment** –The Licensee shall not assign or transfer or purport to assign or transfer any of the Licensee's rights or obligations under the Licence Agreement.
- 10.2. **Announcements** – The Licensee may not make any public announcement or communication (except as may be required by law) concerning the transactions referred to in the Licence Agreement without the Licenser's prior written consent.
- 10.3. **No Partnership** – Nothing in the Licence Agreement creates, implies or evidences any partnership or joint venture between the Licensee and the Licenser or the relationship of principal and agent. Neither party shall hold itself out as being the agent or representative of the other.
- 10.4. **Use of Name** – The Licenser shall ask for the Licensee's written consent for every use of the Licensee's name and logo in advertising and marketing by the Licenser . The Parties agree that Licensee's consent is limited to stating only that the Licensee is a licensee and user of the Questionnaires. In particular, the Licenser agrees not to represent that the Licensee endorses the use of the Questionnaires for any purpose.
- 10.5. **Entire Agreement** – The Licence Agreement constitutes the entire agreement between the Licensee and the Licenser relating its subject matter to the exclusion of all other terms and conditions (including any terms or conditions which the Licensee purport to apply under any purchase order, confirmation order, specification or other document) except where any special terms and conditions are agreed in writing by Licenser. The Licensee warrants that the Licensee have not relied on any representation made by the Licenser or on the Licenser's behalf that is not expressly set out in the Licence 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 the Licenser fraudulently) in relation to any representation which is not specifically set out in these Licence Terms.

- 10.6. **Variation** — No variation of this Licence 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 the Licence Agreement by the Licensor shall not constitute a waiver of the right or remedy or a waiver of any other rights or remedies by the Licensor. No single or partial exercise of any right or remedy under the Licence Agreement by the Licensor shall prevent any further exercise of the right or remedy or the exercise of any other right or remedy.
- 10.8. **Notices** – The Licensor may validly serve a notice on the Licensee under the Licence Agreement at the, Contact Details for the Licensee or such other address in the UK as the Licensee may in writing notify to the Licensor for such purpose.
- 10.9. **Third Party Rights** – Except for the exercise by the University of Oxford and other beneficiaries of the rights expressly granted to them under clause 7.4 of the Licence Agreement, no third party is intended to benefit from any rights under the Licence Agreement.
- 10.10. **Governing Law** - English Law governs the Licence Agreement and the Licensee hereby irrevocably agrees to submit to the exclusive jurisdiction of the English Courts in respect of any dispute or claim arising under or in connection with the Licence Agreement or its subject matter.
- 10.11. **Electronic Signature** – The Parties expressly agree that signatures delivered electronically (by facsimile, email, DocuSign or other means) shall be considered valid, binding and effective on the Parties for all purposes.