CASE STUDY

Language services in the **life-science** sector for **OM Pharma**.

"LINGUISTIC VALIDATION PROCESS APPLIED TO THE TRANSLATION OF A QUESTIONNAIRE FOR A CLINICAL STUDY VIA PROTOCOLS IN ACCORDANCE WITH EMA AND FDA GUIDANCE, WITH INDEPENDENT FORWARD AND BACKWARD TRANSLATIONS BY QUALIFIED TRANSLATORS, AND FIELD-TESTING USING IN-COUNTRY COGNITIVE DEBRIEFING IN A SMALL SAMPLE OF PEOPLE."

SPECIFICS

- Elaborate linguistically validated instruments for a target population aged between 6 to 11 years old based in Hong Kong.
- Line up highly specialised resources to go through the critical steps of our linguistic validation process such as duo-forward translation, back-translation, cognitive debriefing and finalisation.
- Analyse the report from the cognitive debriefing step together with the SMEs so to fine-tune the instruments and produce the final project documentation (Statements of truth and linguistic validation certificate)

ABOUT THE COMPANY

OM Pharma is a global Geneva-based biopharmaceutical company, leader in the prevention of recurrent respiratory and urinary tract infections, also active in the treatment of vascular diseases.

OM Pharma's marketed portfolio includes products for respiratory tract infections, lower urinary tract infections, chronic venous insufficiency, microangiopathies (for example diabetic retinopathy), hemorrhoids and menometrorrhagia (heavy menstrual bleeding). Broncho-Vaxom® and Uro-Vaxom® products are manufactured in Geneva and distributed in 100 countries across the world.

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OBJECTIVES & PROJET SCOPE

OBJECTIVE

OM Pharma's clinical trial team contacted us in the late February 2022 as they planned to translate a questionnaire for a clinical study via established localisation protocols in accordance with EMA and FDA guidance, with independent forward and backward translations by qualified translators, and field-testing using in-country cognitive debriefing in a small sample of people. The client planned the study submission to EC (Ethics Committees) and HA (Hospital Authority) by early April 2022 and first Site initiation visits in July 2022. Translated questionnaires are part of submission package.

PROJECT SCOPE

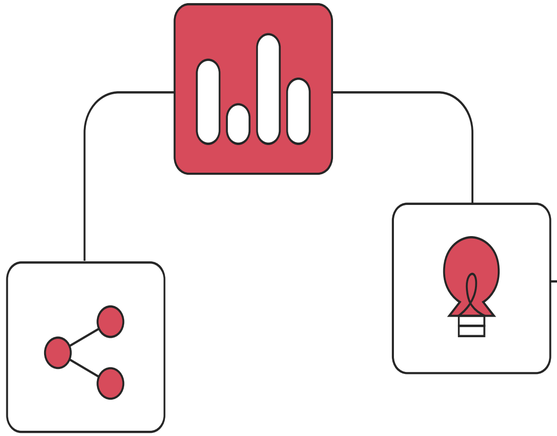
The project encompassed the full scope of the linguistic validation process for a very "niche" target population being children aged based in Hong Kong aged between 6 to 11 years old.

PROJECT-RELATED CHALLENGES:

Once OM Pharma and Transladiem defined the project requirements, we kicked off the work bearing in mind the following challenges:

- The project encompassed the full scope of the linguistic validation process (duo-forward translation, harmonisation, back-translation, reconciliation, cognitive debriefing, finalisation) and this needed to happen in a time-frame of 1 month which was tight considering that the cognitive debriefing step only could take from 7 to 10 working days to get the instruments tested and the reports analysed with the SMEs.
- Collecting all side documentation and material on time, specific to the linguistic validation process such as Statements of truth for all resources utilised, the final cognitive debriefing report checked by SMEs and the stamped linguistic validation certificate.
- The cognitive debriefing step targeted a very “niche” population being children aged based in Hong Kong aged between 6 to 11 years old with rare conditions. We needed to find 5 of these respondents in a tight timeframe in Hong Kong and the instruments needed to be translated in such a way to be easily communicated to the respondents.
- Assessing the authorised level of assistance from doctors, nurses and parents while the instruments were being tested by the respondents since the audience targeted was children.

THE SOLUTION



The dedicated Transladiem team set up an initial meeting to gather the key requirements for this linguistic validation project and gather more information on the project objective, targeted audience respondent's criteria and completion time. Our team then put together the project quote and created a timeline document outlining key dates and steps to go through for our client's instrument to be successfully translated and linguistically validated.

A carefully selected team of linguists and SMEs had been formed, with the relevant background in the life science industry. The terminology linked with the essential points to get answers on, and the phrasing of the queries were very important considering the targeted audience for the instrument was an audience of children, more precisely children aged between 6 to 11 years old. We have first run through the duo-forward translations, producing two translations then for the same source document. We have then analysed the translations and harmonised them to create the best possible version of the translated document. This process is always raising queries among SMEs around the best phrasings and words to be used so to avoid ambiguity and obtain the best answers from respondents depending on what the study is specifically designed for.

Then, we went through the back-translation stage during which we had to translate the content back from the Chinese Traditional translation we just obtained into English again. This is done so the SMEs can check whether there are any discrepancies between the original source text and the final back-translated English copy. If discrepancies are revealed in this process and confirmed as an issue or a risk of ambiguity by the SMEs, this would mean that the Chinese Traditional copy would need attention and rework on that specific point. This reconciliation step is very important to validate the translated Chinese Traditional copy before sending the instrument out for the testing phase and cognitive debriefing step.

Even though they were assisted by their parents, our contacts in Hong Kong who were testing the instruments with the respondents needed to pay utmost attention to seize whether the respondents really understand the queries considering their young age. The answers collected from all respondents allowed our team to fine-tune some of the phrasings. This optimisation is possible at this stage as our contacts have shared feedback on the level of assistance needed by the respondents to answer the queries properly, and the decided outcome is always a low level of assistance and clear understanding of the questions. Based on this last round of feedback, our team validated linguistically the instruments in Chinese Traditional. We have managed to deliver the linguistically validated translated copy on time together with all associated documentation (cognitive debriefing report, statements of truth from all resources, stamped linguistic validation certificate)

RESULTS

- Efficient sourcing of rare respondents on a very short timeframe (5 respondents aged from 6 to 11 years old with rare conditions located in Hong Kong).
- Smooth execution of our linguistic validation process with constant updates to the clinical trial manager on client site.
- Optimised use of the harmonisation, reconciliation, cognitive debriefing and finalisation steps to fine-tune the final deliverable and constantly improve results throughout the whole process.
- Successfully on-time delivery of the linguistically validated instruments and relevant documentation (cognitive debriefing report, statements of truth from all resources, stamped linguistic validation certificate)

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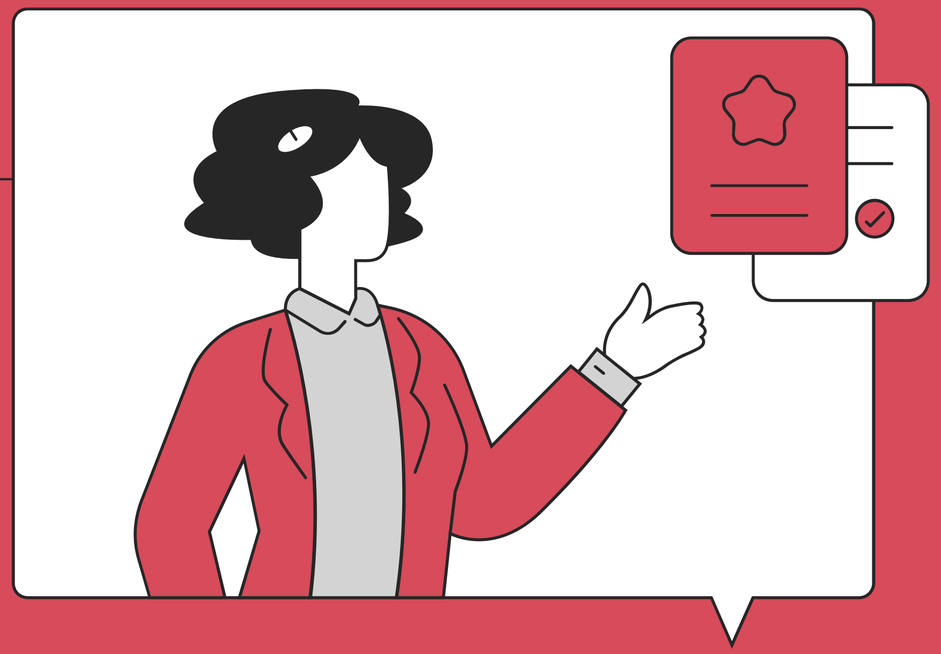


"I have been working with Transladiem in the past 2 years and I have appreciated their professionalism and flexibility. They are always here to provide support and suggestions which make things easier. They are always available to answer questions and provide clear timelines which is important as translation is part of a bigger process. I will work for sure again with Transladiem and I wish the best to the team"

CLINICAL TRIAL MANAGER AT OM PHARMA

PROFESSIONAL LANGUAGE SERVICES FOR THE PHARMA SECTOR

INDUSTRY SPECIALIST AND BESPOKE LINGUISTIC VALIDATION PROCESS

At Transladiem, all is made to ease the linguistic validation process and the localisation of instruments so to offer a seamless experience to our stakeholders. Indeed, our Sales , Account Management and Production teams are proud to rely on industry experts, SMEs and a vast network of partners among the global medical workforce who are happy to accompany our client through the whole process from the initial meetings, through the duo-forward translations, harmonisation, back-translation, reconciliation, cognitive debriefing and finalisation steps. We pride ourselves in respecting EMA and FDA requirements and always make sure to clarify key elements before proceeding (targeted audience, language specifics, testing support either paper or digital, etc)

CUTTING-EDGE TECHNOLOGY

At Transladiem, we put our technology at the service of our clients. Our translation memory technology will help you generate savings and translating consistently through the time. Our Online Review Platform will streamline the review process of the subject matter experts on client side and ease the project management with no more manual handling of files - indeed the review phase is centralised, and its advancement can easily be monitored by our clients. Reports from the cognitive debriefing phase are also benefitting from our technology when they get generated so to segment each of the relevant items in order to ease the way we address them and work on them.

PROFESSIONAL LANGUAGE SERVICES FOR THE PHARMA SECTOR

FOCUS ON QUALITY

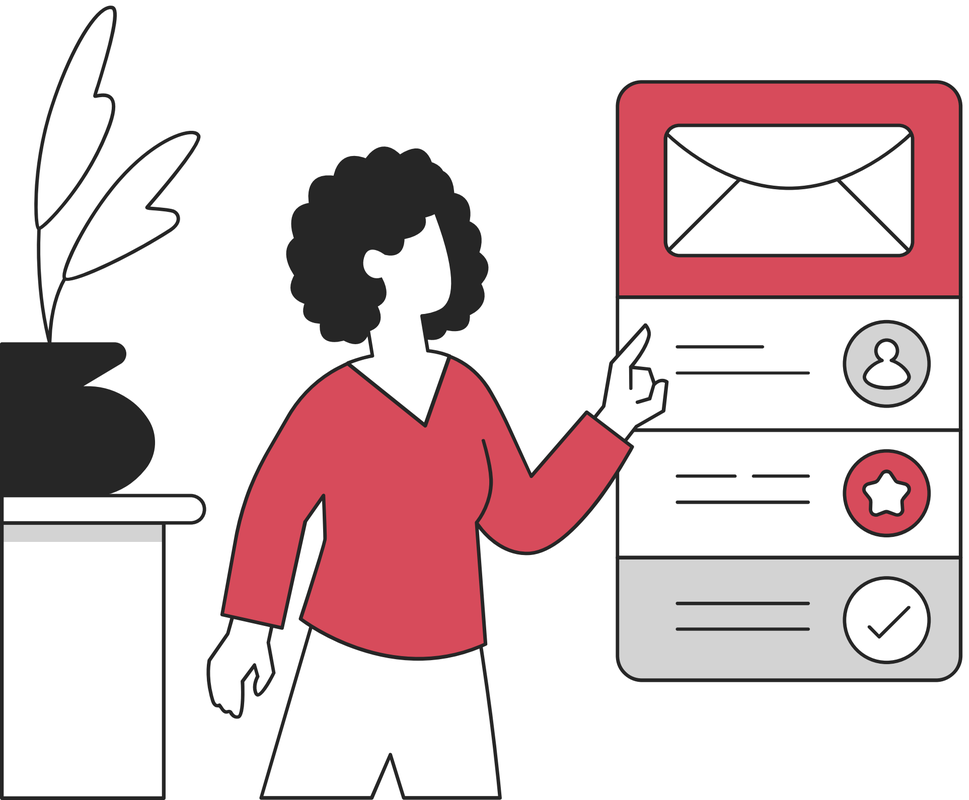
Quality is at the heart of everything we do. Our linguist section process has strict requirements so to allow us to only work with industry-leading translators. We also operate following internationally recognised quality and operational standards such as ISO 9001 and ISO 17100. We ensure that rigid quality assurance processes are in place and performed by our projects managers who streamline the work of our resources (linguists, voice talents, video editors, engineers, etc). Every project step at Transladiem is QA'ed prior to prepping the files for delivery so last adjustments and fine-tuning can occur. Another unique quality-based feature is our enhanced translation process called "Verification & Validation" which have our project managers perform 2 checks during the translation process instead of a single final one. Hence, our translation workflow includes internal checks on the work delivered by both the commissioned project translator as well as by the project proof-reader upon delivery to us, so to make sure that each step of the process is always thoroughly QA'ed and to allow us to react immediately in case of non-conformities.

PERSONAL APPROACH, AGILE PROJECT MANAGEMENT AND TAILORED PROJECT PLAN

Transladiem provides you with a dedicated account manager who will guide you through your next translation or localisation project. We will discuss and gather all key requirements and draft the project plan and the corresponding timeline accordingly so to match your expectations. Client input and feedback are sought continuously, and our highly-flexible and reactive project team is ready to implement planned as well as last-minute changes anytime!

GET YOUR MESSAGE ACROSS

THANK YOU!



DO YOU HAVE ANY QUESTIONS?

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