
LINGUISTIC VALIDATION COURSE

OVERVIEW

Linguistic Validation
Consultant Training for
Medical Translators

Trainer: Nur Ferrante

Developed by Nur Ferrante.





LV COURSE - CONTEXT

Linguistic validation is growing exponentially due to the vast increase in these later years of a demand for the translation and cultural adaptation into multiple languages and variants of Clinical Outcomes Assessments (COAs), mostly Patient-Reported Outcomes (PRO) and Quality of Life (QoL) measures, Clinician-Reported Outcomes (ClinROs), Observer-Reported Outcomes (ObsROs) and Performance Outcomes (PerfOs), as well as preparation and migration of translations for use on electronic platforms (eCOA), and other instruments. The main reason is that multinational clinical trials and medical research is multiplying worldwide, and the instruments need to comply with ISPOR, the PRO Consortium, and the FDA guidelines, which make this service a highly skilled and complex one, but also greatly rewarding in medical humanities terms as well as professionally.

Patients are at the heart of what we do in linguistic validation, and how they feel and function as well as their quality-of-life are increasingly becoming very important aspects in the pharma product development industry.

Through this service, we help patients understand and express how they feel and function in their own language so that they may be able to “have a voice” in medical research and clinical trials. These instruments are also used in usual clinical practice and help diagnose and assess patients in an enormous range of medical conditions.





LV COURSE - OVERVIEW

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WELCOME TO THE LV COURSE FOR BECOMING A LINGUISTIC VALIDATION CONSULTANT

- Would you like to become part of this fastly growing and exciting industry of linguistic validation (LV)?
- Do you wish to open new opportunities for personal and professional development and satisfaction, and to increase your income as medical translator contributing in a valuable and meaningful way?
- It is a great pleasure to welcome you to this linguistic validation (LV) training course. I hope you will find it clear, suitable, and most useful for facilitating the advancement of your medical translation career in this beautiful and rewarding professional field.
- Thank you very much for deciding to invest in your future and for choosing this course.
- Glad to be your trainer!





MEET THE TRAINER – NUR FERRANTE

- Nur Ferrante is a linguist and healthcare provider. She has been working in medical translation and healthcare for over 20 years and specializes in linguistic validation. She has worked in the field for over 10 years and offers the following LV Services:
 - LV Service Development & Implementation (creation, development, and training for LV Services implementation)
 - LV Service Consultancy & Support (audits for quality control, updates, and benchmarking)
 - LV Project Coordination (project lead and linguistic management)
 - LV Project Consultancy for EN-spaES (all LV stages, including patient recruitment, cognitive debriefing interviews, and clinician recruitment)
 - LV Training for medical translators
- Besides translating, teaching and being of value to patients, she loves writing poetry and novels, walking in nature, practicing meditation and spending time with her family.





LV COURSE – PRESENTATION

- This is an independent course that belongs to the field of linguistics, translation, and medicine.
- It is intended for professional development and has been specially designed for training medical translators who wish to work as linguistic validation consultants (LVCs)/in-country consultants/in-country team leaders, or who are so already but want to expand in their knowledge of the specialty.
- You will learn all the required concepts, methodology and “know how” to provide quality services for the Translation and Cultural Adaptation of Clinical Outcome Assessments (COAs) and other medical instruments that are frequently used in clinical trials and medical research.





LV COURSE - OBJECTIVES

- The **main objective** of this course is to provide you with the necessary knowledge and tools to be ready for working in linguistic validation projects with your language pair (right after its completion) for Contract Research Organizations (CROs), medical translation agencies, and other translation agencies who offer linguistic validation services worldwide.
- A few **secondary objectives**:
 - Learning how to be seen and recruited by CROs and translation agencies and how to position yourself in order to become part of their pool of consultants and receive steady work
 - Gaining the necessary confidence to work in LV projects and develop the leadership qualities that will be required
 - Learn how to maintain and increase your rate of projects and how to become the project manager's first choice of consultant for your language pair





LV COURSE – SKILLS & COMPETENCIES

- Skills and competencias encouraged and developed in this course:

General skills & competencies

- Management and planning of tasks and work. Efficient use of time
- Development and use of high cognitive processes: analysis and synthesis, decision making and applying the knowledge in practice, and in new and unknown environments, creativity and critical thinking
- Process management for improvement, quality and innovation: follow-up, monitoring, and self-evaluation. Application of improvement measures and innovation
- To communicate adequately and use the tools and services of the knowledge society. Written and oral communication in English. Selection, evaluation, transformation, and treatment of information and its presentation
- Awareness of team work relevance and development of skills regarding cooperation, efficient negotiation, conflict resolution, coordination and leadership
- Commitment to the professional training environment norms and etiquette, kindness, respect, and regard for the fundamental values of democratic societies
- A sense of cooperation over competition





LV COURSE – SKILLS & COMPETENCIES

- Skills and competencies encouraged and developed in this course:

Specific skills & competencies

- To know the concept of linguistic validation and its purpose and function
- To know your role as a linguistic validation consultant (LVC)/in-country consultant/in-country team leader
- To apply the medical and linguistic knowledge to the process of linguistic validation
- To know how to apply the methodology of linguistic validation in a professional working environment and adapt to each project's needs and variation
- To learn and develop the necessary skills to conduct cognitive debriefing interviews with patients and healthy participants
- To detect and appreciate the different aspects of linguistic validation and its application and importance for patients and society as a whole
- To be flexible, adaptable, and creative to successfully deliver a high quality linguistic validation work
- To embrace the multicultural and diverse environment where linguistic validation is placed
- To recognize your value as linguistic validation consultant and the importance and repercussion of your work in patients' lives





LV COURSE – PREREQUISITES

- For taking this course and succeeding in your LV career, the following requirements are necessary and desirable:
 - A very high level of written English
 - At least 5 years of experience as a medical translator
 - Strict adherence to deadlines
 - A high analytic and synthetic ability
 - High communication skills
 - Compassion towards patients
 - A degree in healthcare or related sciences (desirable but not required) apart from your degree in linguistics or Translation
 - Country of residence the same as your native country (some exceptions apply)





LV COURSE DESIGN & METHODOLOGY

- This LV Course has a self-paced design.
- It consists of the following:
 - Part 1: On-line self-training
 - Readings
 - Power point with audio presentations
 - Self-assessment tests for each module and chapter
 - Final practice and evaluation
 - Part 2: A mentoring and closing evaluation session with the trainer after successfully completing part 1
 - Duration of the course:
 - Estimated dedication time: 75-100 hours
 - Estimated time for completion: 2-3 months
 - After passing the course, you will receive a detailed Certificate of Completion





LV COURSE - ROAD MAP

- Module 1: Introduction
- Module 2: LV Concept
- Module 3: LV Project Methodology
- Module 4: LV Project Workflow
- Module 5: Practice and Professional Placement
- One-to-one mentoring session with the trainer





LV COURSE OVERVIEW – PROGRAM

- This LV course is structured in 5 main modules with units:
- Module 1: Introduction
 - Unit 1(M1): COAs and other measures - What are we working with?
 - Unit 2(M1): Linguistic validation - Translation & cultural adaptation at a glance. Best practices.
 - Unit 3(M1): LV Process - A snapshot
 - Unit 4(M1): linguistic validation consultant (LVC)/in-country consultant/in-country team leader
 - Test for module 1
- Module 2: LV Concept
 - Unit 1(M2): COAs, types, and other measures
 - Unit 2(M2): Linguistic validation: the concept
 - Test for module 2





LV COURSE OVERVIEW – PROGRAM

- Module 3: LV Project Methodology
 - Unit 1(M3): Preparation
 - Translatability assessment
 - Concept elaboration
 - Unit 2(M3): Forward Translation (FT) & reconciliation
 - Unit 3(M3): Backward translation (BT), BT analysis & Harmonization
 - Unit 4(M3): Cognitive debriefing & interviews
 - Unit 5(M3): Clinician review
 - Unit 6(M3): Review & final check
 - Unit 7(M3): Migration & electronic implementation of eCOAs
 - Test for module 3
- Module 4: LV Project Workflow
 - Unit 1(M4) LV Workflow dynamics
 - Test for module 4
- Module 5: Practice and Professional Placement
 - Practice exercise and final exam for the module





THANK YOU!

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