Allen Yang

Professional Life-Scinece Translator

Subject Matter Expert | Life-Science

allenyang.translator@gmail.com

+8615828047453

Soochow, China

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BRIEF INTRODUCTION

I am a pharmaceutical and healthcare subject translator with 10 years of experience in translation and I also have 8 years of experience in the pharmaceutical industry and clinical trial industry.

EDUCATION

Biotechnology
Sichuan University of Science & Engineering
2009 - 2013

CERTIFICATES

CATTI-2

CAT TOOL

Trados

MemoQ

TRUSTED BY

ICON
"ICON, one of the Top 10 Contract Research Organisations (CROs), is an Irish- headquartered developer of drugs to the pharmaceutical, biotechnology, and medical device industries "

IQVIA
"IQVIA, one of the Top 10 Contract Research Organisations (CROs), is an American multinational company serving the combined industries of health information technology and clinical research. "

SDL
"SDL, a multinational professional services company, specializes in language translation software and services. "

Language Scientific
"Language Scientific, a US-based translation and localization company, specializes in providing medical, engineering, and technical translation and localization services in all European, Asian, Middle Eastern, African, and American languages"

SPECIALIZED FIELDS

Clinical Study | Non-clinical Study | Medical | Health-Care | CMC | Pharmacovigilance | Pharmaceutical (eCTD Format) | Patient Documents | Regulatory Affairs | Lab

Part of The Study Name of The Projects Related

STUDY SUBTITLE

An International, Multi-Center, Open-Label, Randomized, Phase III Trial of (PRODUCT NAME) versus Treatment of Physician Choice in Patients with Metastatic Triple-Negative Breast Cancer Who Received at Least Two Prior Treatments

A Single-Arm, Single-Center, Non-Randomized, Open, Efficacy and Safety Trial of (Product Name) Combined with (Product Name) for The Treatment of Advanced Hepatocellular Carcinoma with Failure or Intolerance of Previous Systemic Chemotherapy or Targeted Therapy

An International, Multi-Center, Open-Label, Randomized, Phase III Trial of (PRODUCT NAME) versus Treatment of Physician Choice in Patients with Metastatic Triple-Negative Breast Cancer Who Received at Least Two Prior Treatments

A Phase II Open-Label, Study of (PRODUCT NAME) in Metastatic Urothelial Cancer After Failure of Platinum-Based Regimen or Anti-PD1/PD-L1 -Based Immunotherapy

A Phase 3 Study of (PRODUCT NAME) versus Treatment of Physician's Choice (TPC) in Subjects with Hormonal Receptor-Positive (HR+) Human Epidermal Growth Factor Receptor 2 (HER2) Negative Metastatic Breast Cancer (MBC) Who Have Failed at Least Two Prior Chemotherapy Regimens

A Phase Ib/II Open-label, Multicenter, Randomized Umbrella Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-based Treatment Combinations in Patients with Metastatic Triple Negative Breast Cancer (Morpheus TNBC)

A Single-Arm, Single-Center, Non-Randomized, Open, Efficacy and Safety Trial of (PRODUCT NAME) Combined with (PRODUCT NAME) for The Treatment of Advanced Hepatocellular Carcinoma with Failure or Intolerance of Previous Systemic Chemotherapy or Targeted Therapy

A Global, Randomized, Phase 3, Open-Label Study of (PRODUCT NAME) versus Platinum-Based Chemotherapy in First-Line Treatment of Patients with Advanced or Metastatic PD-L1 + Non-Small Cell Lung Cancer

A Phase 1/2 Non-Randomized, Open-Label, Multi-Cohort, Multi-Center Study Assessing the Clinical Benefit of (PRODUCT NAME) Combined with (PRODUCT NAME) for the Treatment of Participants with Advanced Unresectable or Metastatic Skin Cancer

An Open-Label, Dose Escalation and Cohort Expansion FIH Study of the Safety, Tolerability, Activity and PK of REGN 3767 Administered Alone or in Combination with REGN2810 in Patients with Advanced Malignancies

A Phase II Single-arm Trial to Investigate Tepotinib in Stage IIIB/IV Adenocarcinoma of the Lung with MET Exon 14 (METex14) Skipping Alterations after Failure of at Least One Prior Active Therapy, including a Platinum-doublet-containing Regimen

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Details of Projects Finished

PHARMACEUTICAL

Chemistry, Manufacturing, and Controls (CMC)
Description of Manufacturing Process and Process Controls, Control of Materials, Controls of Critical Steps and Intermediates, Process Validation and/or Evaluation, Manufacturing Process Development, Impurity Study, Analytical Procedures, Validation of Analytical Procedures, Batch Analyses, Justification of Specification, Stability Study

Nonclinical Study
Pharmacodynamics Study, Pharmacology Study, Pharmacokinetics, Toxicology Study

Clinical Study
Bioavailability (BA) Study, Comparative BA and Bioequivalence (BE) Study, In Vitro - in Vivo correlation Study, Reports of Bioanalytical and Analytical Methods for Human Studies, Plasma protein binding Study, Reports of hepatic metabolism and drug interaction studies, Reports of studies using other human biomaterials, Human Pharmacokinetic (PK) Study, Human Pharmacodynamic (PD) Study, Efficacy and Safety Study

PHARMACOVIGILANCE

Events REPORT
More than 300 such reports translated including AE, SAE, ADR, UADR and SUSAR

PATIENTS OR SUBJECTS RELATED DOCUMENTS

Informed Consent Form(ICF)
More than 200 ICFs translated including Exploratory ICF, Biomarker ICF, Tissue Screening ICF, Pregnant Partner Master ICF...

Admission Note, Records of Ward Round, Discharge Note
Such notes or records with more than 200,000 characters or words have been translated

Details of Projects Finished

LAB

Laboratory Manual for Pfizer
ICON Laboratory Services

Laboratory Manual for Bristol-Myers Squibb
ICON Laboratory Services

Laboratory Manual for Ascendis Pharma Growth Disorders A/S
ICON Laboratory Services

Laboratory Manual for Novartis
ICON Laboratory Services

Laboratory Manual for MSD
ICON Laboratory Services

Laboratory Sample/Specimen Collection Flowchart for Eli Lilly & Company
Q2 Solutions (IQVIA)

Laboratory Sample/Specimen Collection Flowchart for Bristol-Myers Squibb
Q2 Solutions (IQVIA)

Laboratory Sample/Specimen Collection Flowchart for Takeda Pharmaceuticals
Q2 Solutions (IQVIA)

Laboratory Sample/Specimen Collection Flowchart for BeiGene, Ltd
Q2 Solutions (IQVIA)

Laboratory Sample/Specimen Collection Flowchart for Novartis
Q2 Solutions (IQVIA)

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OTHER

Investigator's Brochure | Study Site Document | Certificate of Analysis | Staff Qualification | Site Master File | EHS | Pharmacopeial Forum | Nursing | FDA Guidance | ICH Guideline | FD&C Act | USP | Hospital Administration | Good Laboratory Practice | Good Manufacturing Practice | Good Clinical Practice | Risk Management | Clinical Statistics | Medical Hand Book

Positive Feedback

TRANSLATION AGENCY

Allen has extensive knowledge in pharmaceutical/regulation industry. He is professional, detailed oriented and willing to go the extra mile to help. It has been a pleasure working with him!
Project Manager

Allen is one of the most professional individuals I have encountered in this industry he understands the project requirements and upholds quality consistently. I would recommend him to anyone.
Project Manager

It's a pleasure to work with him. Very professional, competent and kind.
Project Manager

CRO COMPANY

Allen is a great guy in the pharmaceutical industry who always make awkward pharmaceutical regulatory readable, intelligible and executable. This guy is not only a translator but also an expert who got deep comprehension in the pharmaceutical industry. Definitely willing to work again!
RA Manager

Great cooperation with Allen. Best translation quality and very professional in pharmaceutical!
RA Manager