Wound Market Consulting

Clinical Evidence

Wound Market Consulting…

Combining Wound Care Industry experience with the Design and Conduct of Clinical Evidence Programmes for Medical Devices for Wound Care

Wound Market **Consulting**

Our Method

- Understand the basics – your strategy and objectives, your resources and priorities.
- Recommend the design of Clinical Evidence most closely aligned with your objectives, budget and timetable.
- Set up the Study Design Team – our Medical Director, our Project Management team, any relevant external specialists and your team.
- Design the study to ISO 14155-1 with reference to the EWMA guidelines for clinical trials. Recommend investigators and study centres and carry out Site Feasibility reviews.
- Project manage and deliver Regulatory Approval, Site negotiations, Study set up, conduct and close down, statistical analysis and final reports.
- Write for publication and advise on publication strategy and the communication strategy for the papers.

Our Resources

WMC has a core team of Clinical Research Specialists, supported by CRAs (monitors) local to the study sites. Studies are managed by the UK-based Project Team directly with the sites and through the local CRAs.

Database set up and management is provided by our partner ELC s.r.o in the Czech Republic and India.

This flat hub and spoke structure helps to keep costs down whilst delivering experienced professional teams.

To Study Design we bring skills and experience in Clinical Wound Care:

- Strategies for Reimbursement
- Meta-Analyses and Literature Reviews
- Statistical Modelling
- Health Economics
- Regulatory Affairs
- Marketing for Wound Care
- Clinical Trial Management
- Design of data collection processes

Quality Assurance

QA and Quality Control is maintained through the use of WMC Standard Operating Procedures (SOPs), compliance with the provisions of ICH-GCP relevant to medical devices, ISO 14155-1 and US FDA regulations for the conduct of medical device studies. A Client's SOPs may be adopted if required.

WHY YOU SHOULD CONSIDER USING WOUND MARKET CONSULTING FOR YOUR WOUND CARE CLINICAL EVIDENCE PROGRAMMES…

- We **Specialise in Wound Care** and bring in international multi-disciplinary wound care experience from product concept to marketing to the design of your whole programme.
- We bring an **Experienced Commercial Perspective** to the discussion of which programme and audience will best achieve your goals.
- We have an overview of the **Wound Care Centres** suitable for your studies.
- We design and conduct solely trials and evidence programmes in wound care, so are very aware of the **Opportunities and Pitfalls in Wound Care Trial Design**, execution and the publication of final results.
- We conduct **Literature Reviews and Statistical Modelling** as part of the Study Design process.
- Our hub and spoke structure keeps us **flexible** and enables us to adapt to any changes in your objectives and to offer **a Full "Turn-Key" Service and to Keep Costs Down**.

Clinical Studies

Study Design	Location	Wound Aetiology	No. of Subjects
Cohort Study-single arm –single centre	Sweden	Leg Ulcers	20
Case Series-multi-centre	England	Leg Ulcers	30
Case Series – single centre	England	Leg Ulcers	5
Registration Study (CE Mark) single centre	Czech Republic	Leg Ulcers	10
Case Series-multi-centre	Czech Republic	Diabetic Foot Ulcers	15
Randomised Controlled Trial-single centre	Germany	Post-surgical	70
Cohort Study-single arm	Italy	Diabetic Foot Ulcers	20
Cohort Study – single arm multi-centre	UK	Various wounds	30
Case Series –multi-centre	UK	Compromised skin	10

Organisation

Our People

Andrew Adams

Managing Director

More than 20 years' experience in bringing wound care products to market across a range of European countries.

Experienced in start-ups and product development, as well as bringing mature products to new markets. Previous roles and experience include Regional Vice President for ConvaTec, for Scandinavia and Central & Eastern Europe; Managing Director of Insense Ltd (biotech and woundcare), non-executive director on medical device start-ups, fund-raising for new businesses.

Mr Adams is a lay member of the European Wound Management Association, the Societe francaise et francophone des plaies et cicatrisations and the Deutsche Gesellschaft für Wundheilung.

Wound Market Consulting is a corporate sponsor of the German "Initiativ für chronische Wunden", the largest of the German wound care societies.

Marion Byford

Clinical Trial Project Manager

Registered Pharmacist and member of the Institute of Clinical Research with over 30 years' experience of Clinical Trial Project Management within the Pharmaceutical and Biopharmaceutical sector.

Ms Byford has experience of all aspects of preparing and conducting Clinical Trials from Phase I to IV, both in the UK and Europe. She has worked on studies sponsored by Roche, ER Squibb, Dainippon Sumitomo, Schering Health, Mitsubishi Pharma, Wyeth, Hoechst and Boots amongst others. Since 1991 Ms Byford has worked as an independent Clinical Research Consultant.

Her areas of expertise include Project Management, Protocol Writing, Case Report Development, Monitoring and Regulatory Affairs for clinical trials.

Dr Benaka Karanth BAMS, M.Sc

Clinical Trial Project Mgr/ Administrator

Has extensive experience in the Health Care and Clinical Research Industry. He has an MSc in Clinical Research from Cranfield and is a qualified Ayurevdic Physician.

Dr Karanth has been involved in Clinical Research since 2008, specialising in Clinical Operations and Essential Document Management. He has worked as a Clinical Research Associate for Reliance Life Sciences and Trial Master File specialist for Phlexglobal.

His key strengths include Clinical Trial Designing and Monitoring, Medical Writing, Clinical Research Management and Quality Control of trial related documents.

Dr Létal RNDr

Biostatistician

Is a Statistician with more than 28 years of experience in biometrics, including 8 years in clinical trial statistical analysis and in excess of 20 years in biometrics research & lecturing.

He has worked at several international CROs and pharmaceutical companies including Advanced Drug and Device Services (France) and Novo Nordisk (Denmark), managing statistical analyses and reporting for clinical trials phase I-IV in a variety of therapeutic fields. He has been the principal statistician for more than 20 multi-centric clinical projects and primary administrator for two analytical Euro Conferences.

Dr Letal's strengths include SAS programming and statistical methodologies of generalised mixed models, linear and non-linear regression analysis, survival analysis, categorical analysis, multivariate methods, FDA and ICH guidelines (including CDISC
standards) and the design of data processing, programming and statistics SOPs.

He is also a long standing member of the International Society of Clinical Biostatisticians (ISCB).