VAN HOEF CONSULTING

In support of the biopharma and biotech industry in improvement of disease outcome

Consulting & Services

CR&D Phase I-IV, Medical Affairs,

includes pharmacovigilance and regulatory

Specialization

- Hematology
- Hematopoietic stem cell transplantation
- Oncology

- Chemotherapy and small molecules
- Biologics, targeted- and immune therapeutics
- Cell therapies

Organisation

VAN HOEF CONSULTING

Girardstrasse 19
2540 Grenchen
Switzerland

Mobile: 0041-76-7610368
Mobile: 0031-6-124 33616
vanhoef@vanhoefconsulting.com

Van Hoef Consulting – Advice & Services

Therapeutic areas

- Hematology
- Hematopoietic stem cell transplantation
- Oncology
- Other therapeutic areas on request

Experience

Clinical development, the launch phase & medical affairs, including pharmacovigilance and regulatory aspects

Products

- Chemotherapy and small molecules
- Biologics, targeted- and immune therapeutics
- Cell therapies

Phases of development

- Phase I
- Phase II-III
- Phase IV
- Observational studies

Clinical research

- Clinical development planning
- Medical and scientific advice
- Study design
- Study synopsis
- Protocol development support
- Review of, and input in study documents
- Investigator selection
- Investigator meetings
- Medical and safety monitoring
- Data review and reporting
- Clinical study report review
- Abstracts, presentations, publications

Van Hoef Consulting – Consulting & Services

Medical Affairs

- Scientific and medical advice
- Development of medical affairs plan
- Advisory board development and support with execution
- Interactions with KOL/investigators
- Review and sign off on scientific and promotional materials
- Review and management of investigator initiated studies
- Training and education

Regulatory and pharmacovigilance assistance

- Data safety monitoring board development
- AE/SAE monitoring, signal detection, risk assessment
- Review/input on periodic safety reports
- Regulatory strategy planning support
- Market authorization applications: input, review of clinical overview, summaries of safety or efficacy, clinical study reports

Support of clinical research operations

- CRF review
- CRA training

Other business support services

- Review of clinical data packages for in/out licensing
- Market research and assessment

Experience with all hematological malignancies and many solid tumor indications.

Experience

Marlies Van Hoef, MD, PhD, MBA, board certified as internist, oncologist and hematologist, worked in academia, in industry in clinical development and medical affairs, at a CRO and at the Swiss regulatory agency in market authorization, at transplant and cancer registries and as consultant mainly in the therapeutic areas oncology, hematology and hematopoietic stem cell transplantation.

A resume can be provided on request. I would be delighted to serve your company.

M: 0041-76-7610368 ● M: 0031-6-124 33616

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