

Evnia

To Strive • To Seek • To Find

Regulatory / Clinical / Real Word Evidence

Market Access Services for Biotechnology

Bringing Regulatory and Clinical Vertical integration **around the world** from **start-to-market** and beyond



* Evnia, means smart, articulated thinking in Greek



Evnia Group



- ✓ **European Union
Authorised Representative**
- &**
- ✓ **United Kingdom
Responsible Person**

- ✓ **Regulatory & Clinical Affairs**
- ✓ **Post Market Clinical Follow Up**
- ✓ **Clinical Evaluation**
- ✓ **Real World Evidence (RWE)**

- ✓ **Patient Treatment**
- ✓ **Real World Evidence**

 **213**
international
clients
...and counting!



UNIVERSITY OF
BIRMINGHAM



جامعة قطر
QATAR UNIVERSITY



HARVARD
UNIVERSITY



UNIVERSITY OF
OXFORD

WHAT DO WE DO?



Through Regulatory, Clinical Affairs & Health Economics
We bring biotechnology innovation to the market

WHAT WE DO

Bringing Biotechnology in the Market



**Fast access
to market**



**Reduced Risk
of investment**



**International
Market Access**



- Start ups
- Established BioTech
- Multinational Biotech
- Investors

- Implement Regulatory Pathway
- Conduct Clinical Affairs
- Conduct Health Economics
- Investors

Idea



Market

A holistic approach to device lifecycle



Development of Med Tech & IVDs

Regulatory Affairs / Preclinical Development / Technical Documentation / Quality Management / Clinical Affairs

Idea / IP

Product Design
Proof of Concept
Feasibility

Verification

Validation

Design
Transfer

QMS
Technical
Documentation

Regulatory
Approval

Post-Market
Surveillance

✓ **Preliminary Regulatory Affairs Plan:** classification based on methodology/ technology

✓ User Requirements Specifications
✓ Design Input
✓ Prototype/ Assay Development
✓ Product performance specifications

✓ Product Specifications
✓ Risk Management
✓ V&V plan
✓ Usability files
✓ Software V&V
✓ Electrical Safety
✓ Stability
✓ Control materials
✓ Establishment of Acceptance Criteria

✓ Scientific Validity
✓ Analytical Performance
✓ Clinical Performance (Performance Studies when needed)
✓ Performance Evaluation

✓ Design finalization
✓ Preparation of production records
✓ Implementation of GLP
✓ Manufacturing instructions
✓ Quality control planning

✓ **EU & US:** QMS certification under ISO 13485
✓ Compilation of Design and Development File (DHF or Technical File)

✓ **EU:** Conformity Assessment per class & CE Marking – Involvement of EMA for CDx
✓ **US:** Submission of 510(k) or PMA or De Novo

✓ **EU:** Post-Market Performance Follow-Up (PMPF), Vigilance, SSP EUDAMED
✓ **US:** Post-Market Performance Studies (when needed)

✓ **Consultation and Regulatory Affairs Support and Writing Services** for the development of the required documentation

✓ Development of Processes and Templates
✓ Development of Testing Protocols
✓ Coordination of Testing
✓ Writing of respective Reports
✓ Clinical Affairs including development of clinical strategy, respective processes & templates and execution of activities from start-up to close-out
✓ Data management
✓ GDPR requirements management
✓ Statistics / Biostatistics

✓ Development of Quality Management System
✓ Regulatory Support towards certification
✓ Audit preparedness support
✓ Development of DHF and/or Technical File

✓ Regulatory Affairs Support
✓ Development of Submissions to Authorities
✓ Management of Communication with Competent Authorities and Notified Bodies

✓ Regulatory Affairs Support to design the PMS Strategy
✓ Real-world monitoring of the IVD: collection, management and reporting of vigilance and real-world data
✓ Development of required reports
✓ Management of Communication with Competent Authorities and Notified Bodies

Bringing Innovation in the market

Regulatory and clinical excellence

Working with

- Start-Ups
- SME
- Multinationals
- Governments



About Evnia's Experience



2015
Founded
in **Copenhagen**
Denmark



International Clients
213

2020, 2021
2022, 2023

Awarded within
**10 best compliance
companies in Europe**
for 2020,
by PharmaTech Europe

AWARDED



2023

Evnia
has been awarded with a
**Borsen's Gazelle
award**

AWARDED

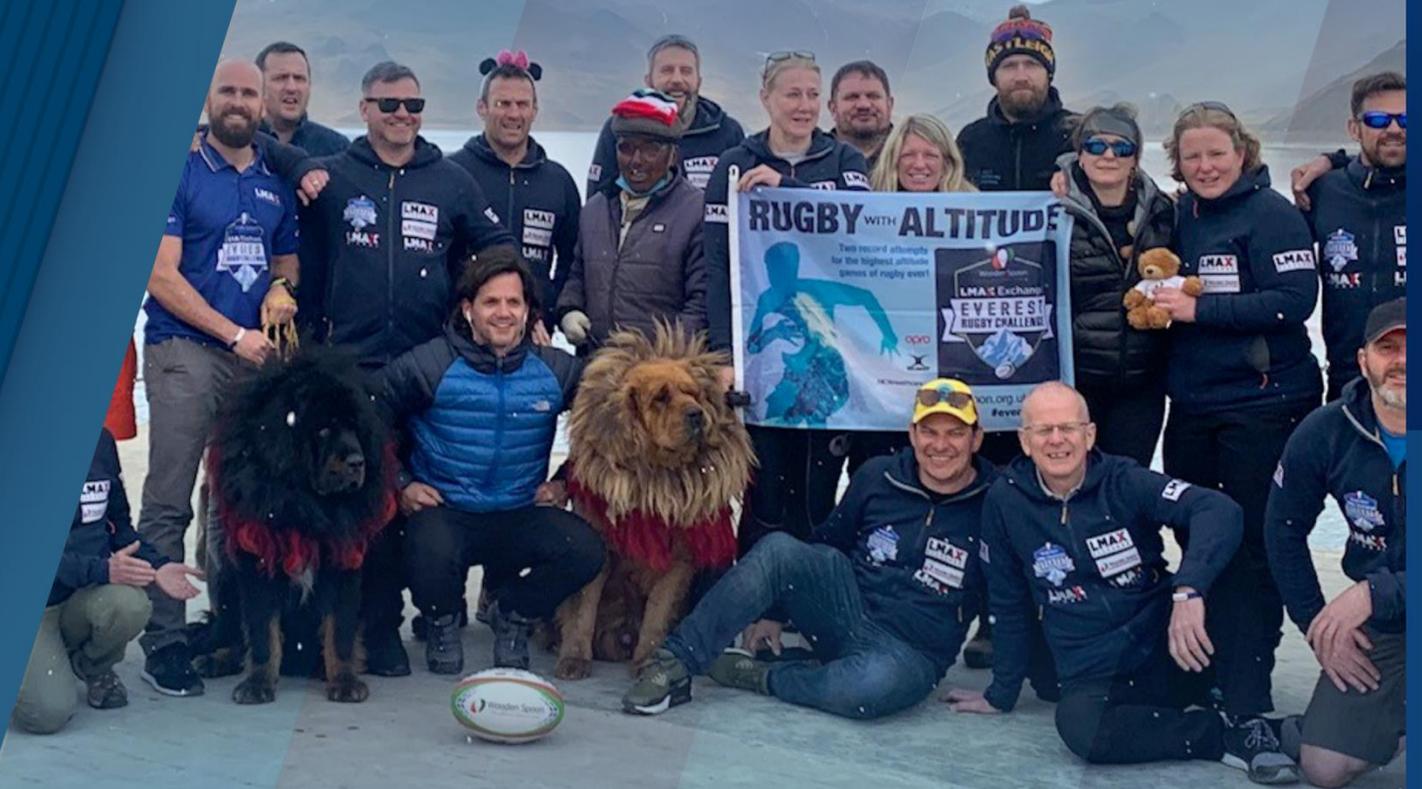


Our Team

Evnia offers centralised **CER /PMCF & Clinical services** that include a cross-functional team:

- Medical Writers
- Medical Doctors
- Usability & Validation Engineers
- Biocompatibility Experts
- Risk experts
- Regulatory Affairs Experts
- Biostatisticians
- Quality Management System (QMS)

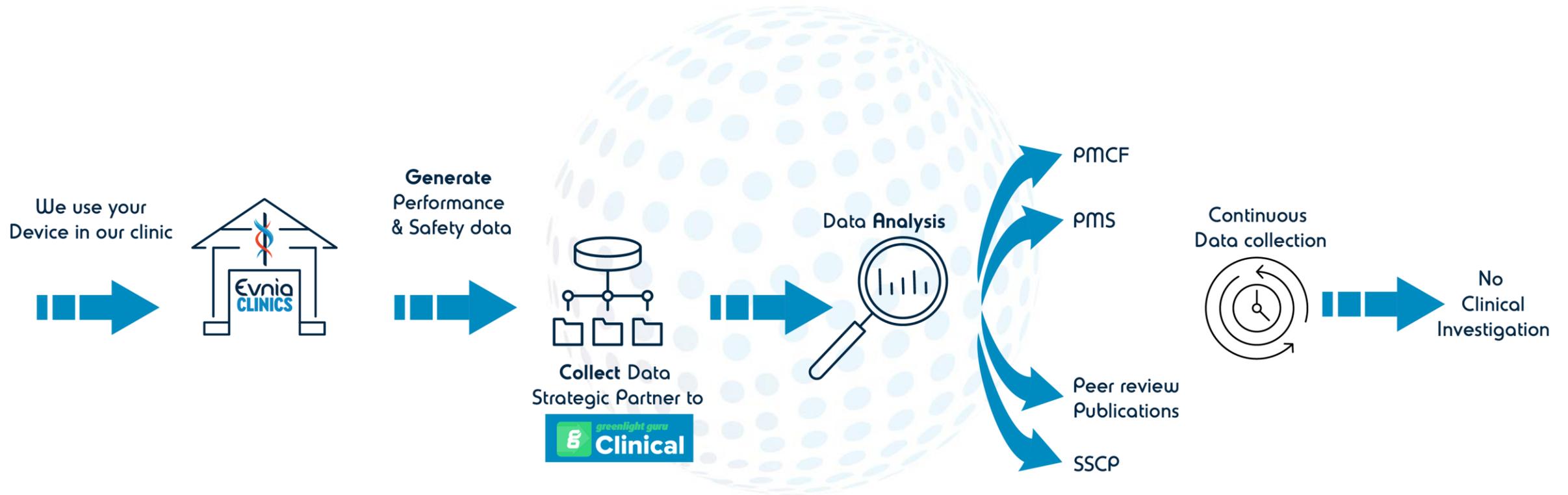
**Average Medical Device Industry
experience between 15-20 years**



Access to clinical sites for clinical data and Real-World evidence



Our Process for Clinical Experience Data



Our Solutions



Our Software Solution

Vigilance data feeding to Risk Management / PSURs / CERs / PMS



Contact

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