tranScrip

A Specialist Pharmaceutical Consultancy

Providing strategic expertise, therapeutic experience and operational excellence across the entire product lifecycle.

Our purpose is to expedite the development and commercialisation of products for the benefit of patients worldwide.

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Early Development

- Target and indication evaluation, product strategy, initial TPP
- Preclinical programme optimisation for FIH readiness
- Design and strategy for early development to PoC
- Full-service delivery of complex, first-in-human trials
- Dose/schedule finding and optimisation
- Stage specific clinical pharmacology packages

Clinical Development

- Strategy, planning, and leadership for Development for Launch
- Trial design to meet regulatory and commercial needs
- Complex data review, interpretation and recommendations
- Selection, management and oversight of CROs and vendors
- Medical monitoring and oversight
- Full-service delivery for orphan indications

Commercialisation

- Strategic commercial partnership
- Market understanding and strategic marketing
- Launch planning and readiness
- Commercial resource planning
- Portfolio strategy
- Investor, partnership and out licensing readiness

Clinical Operations

- Strategic programme planning with timelines, risks, costs
- Full-service delivery of small clinical studies (<50 patients)
- CRO and vendor selection, management, oversight
- Trial feasibility and site-level protocol assessment
- Negotiation and management of contracts and budgets
- Monitoring, SOPs, audits, and GCP inspection readiness

Regulatory Affairs

- Global regulatory strategy
- Health Authority interactions and special designations
- MAA, NDA and BLA strategy, support and submission
- CMC, medical devices and diagnostics
- Regulatory clinical trial strategy and submission
- Medical writing and publishing

Market Access

- Strategic market access partnership and roadmap
- Strategic pricing and launch sequence optimisation
- Evidence gap identification and RWE strategic planning
- Value propositions, dossiers and HTA submission support
- Payer Insights gathering
- Payer and stakeholder engagement materials

Pharmacovigilance and Risk Management

- PV vendor selection, oversight and management
- Bespoke Global Regulatory Health Authority responses
- Data and Safety Monitoring Board set up and facilitation
- Signal detection and management, incl. label development
- End-to-end case management process
- EU/UK QPPV and qualified GVP auditing

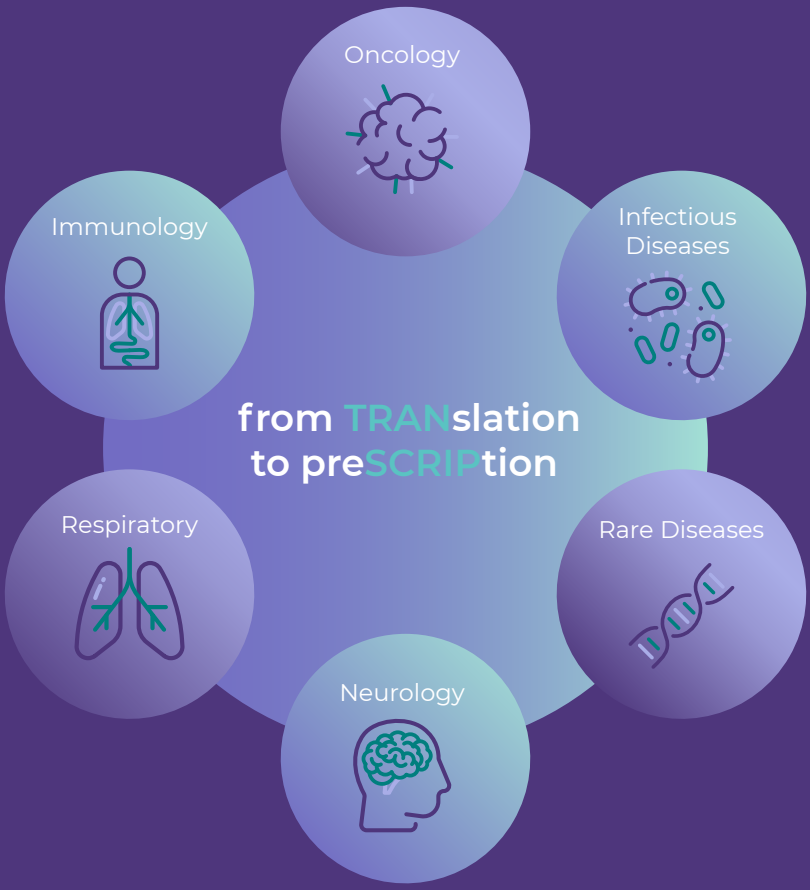
Medical Affairs

- Medical leadership, transformation and capability build
- Strategy and tactical planning
- Stakeholder management, analytics and insights generation
- RWE and late-stage clinical trial strategy and design
- Publications, medical writing and scientific messaging
- Training development and delivery

Our deep expertise spans all therapeutic areas, enabling us to deliver tailored support that meets your specific needs.

We have extensive experience with small molecules, biologics, medical devices, and combination products, addressing both common and rare diseases.

Whether your project requires a comprehensive development programme or specialist services, we are committed to accelerating your product's journey from **TRAN**slation to pre**SCRIP**tion.



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