tranScrip

A Specialist Pharmaceutical Consultancy

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

We exist to expedite the development and commercialisation of products for the benefit of patients worldwide.

Visit transcrip-group.com

Support from TRANslation to preSCRIPtion

Discovery | Pre-clinical | Phase 1 | Phase 2 | Phase 3 | Registration | Post-licensing

Early Development

- Product Strategy and Target Product Profile
- Design and implementation of IND-enabling programmes
- Strategy and design of early development plan to PoC
- Full service delivery of complex, first-in-human clinical trials
- PK, PD, biomarker strategy and analysis
- Formulation development strategy

Commercialisation

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

Regulatory Affairs

- Regulatory strategy and execution
- Leading interactions with regulatory agencies globally
- CMC, medical devices, clinical and non-clinical pathways
- Regulatory clinical trial strategy and support
- Medical writing, publishing and submissions
- Regulatory compliance, quality systems and audits

Pharmacovigilance and Risk Management

- Pre-approval drug safety management
- Signal detection and management
- Data and Safety Monitoring Board activities
- Safety report preparation e.g. DSURs, PSURs, RMPs
- End-to-end case management process
- EU/UK QPPV and qualified GVP auditing

Clinical Development

- Extensive therapeutic area knowledge
- Strategy, planning, delivery and leadership
- Comprehensive clinical trial design
- Complex data review, interpretation and recommendations
- Selection, management and oversight of CROs and vendors
- Medical monitoring

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

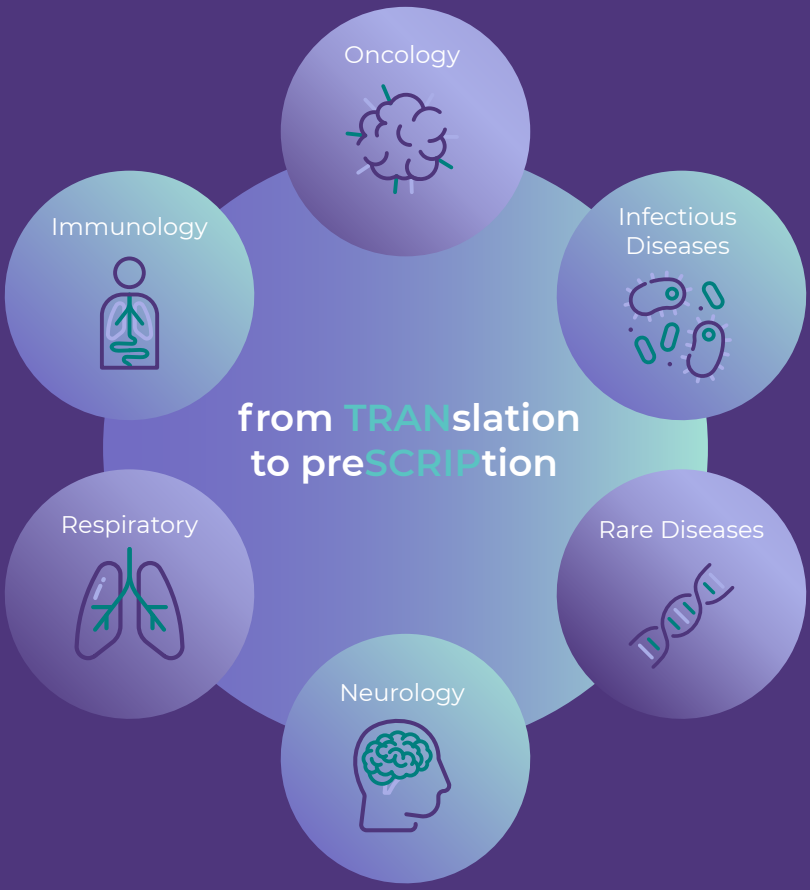
Medical Affairs

- Medical leadership, transformation and capability build
- Strategy and tactical planning
- Data analytics and insights generation
- Evidence generation and RWE
- Medical external scientific engagement
- Stakeholder management

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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