tranScrip

Specialist Pharmaceutical Consultancy

Visit transcrip-group.com

Support from **TRAN**slation to pre**SCRIP**tion

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

tranScrip is a highly specialist pharmaceutical consultancy that provides strategic expertise, therapeutic experience and operational excellence across the entire product lifecycle.

We build product strategies as well as design and execute development programmes and commercialisation activities.

Our experienced physicians and scientists, together with our regulatory, clinical and commercial experts, offer truly flexible bespoke solutions and support to maximise the value of products.

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

Early Development

- Product strategy and Target Product Profile
- Design and implementation of IND-enabling programmes
- Strategy, design and delivery of clinical pharmacology and proof-of-concept studies
- PK/PD strategy and analysis
- Formulation development strategy

Portfolio Management and Commercialisation

- Target Product Profile evaluation
- Portfolio optimisation
- Market understanding
- Commercial launch readiness

Regulatory Affairs

- Regulatory strategy and agency interactions
- Authoring of regulatory documentation
- Management of global regulatory submission processes
- Regulatory compliance and quality systems

Drug Safety, Pharmacovigilance and Risk Management

- Pre-approval drug safety management
- Signal detection and management
- Data and Safety Management Board activities
- Safety Report preparation – DSURs, PSURs, RMPs

Clinical Development

- Extensive therapeutic area knowledge
- Clinical development strategy and planning
- Comprehensive clinical trial design
- Complex data review, interpretation and recommendations
- Selection and team oversight of CROs and vendors
- Medical Monitoring

Medical Affairs

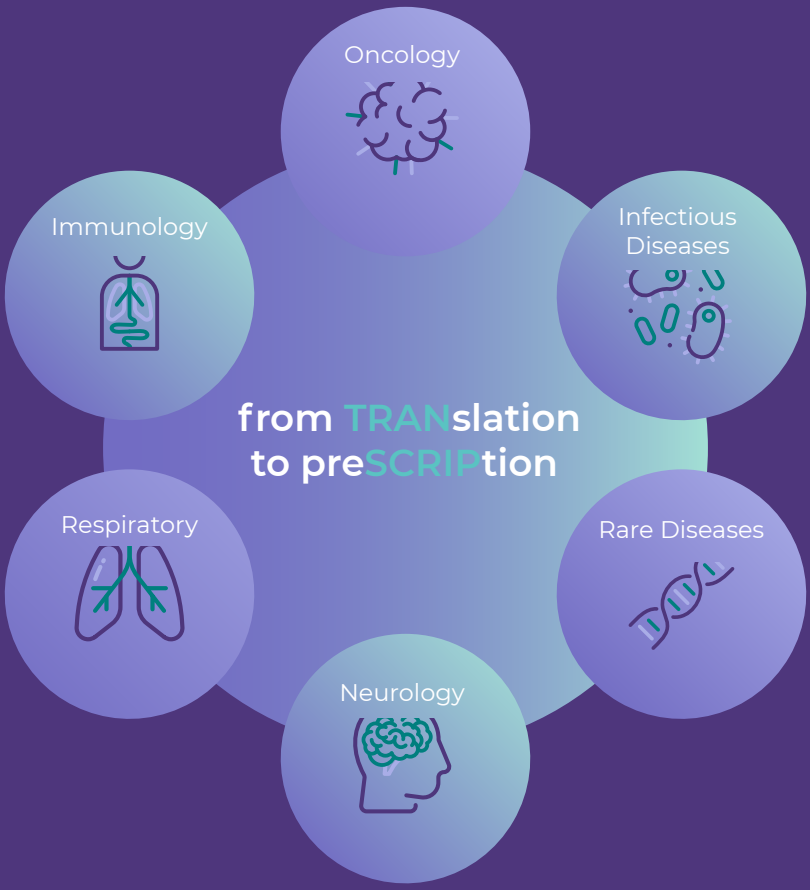
- Lifecycle management planning
- Launch preparation and training
- Stakeholder identification and engagement
- Design of phase 4 clinical trials

Our extensive expertise spans all therapeutic areas, ensuring that we can provide tailored support for your specific needs across the entire product lifecycle.

Our proficiency spans small molecules, biologics, devices and combination products, covering both rare and common diseases.

This diverse therapeutic experience enables our experts to maximise the value of your products, ensuring optimal outcomes.

Whether your project requires a comprehensive development programme or specialist service, we are committed to accelerating your journey from product translation to prescription.



tranScrip

Visit
transcrip-group.com
Email
info@transcrip-group.com