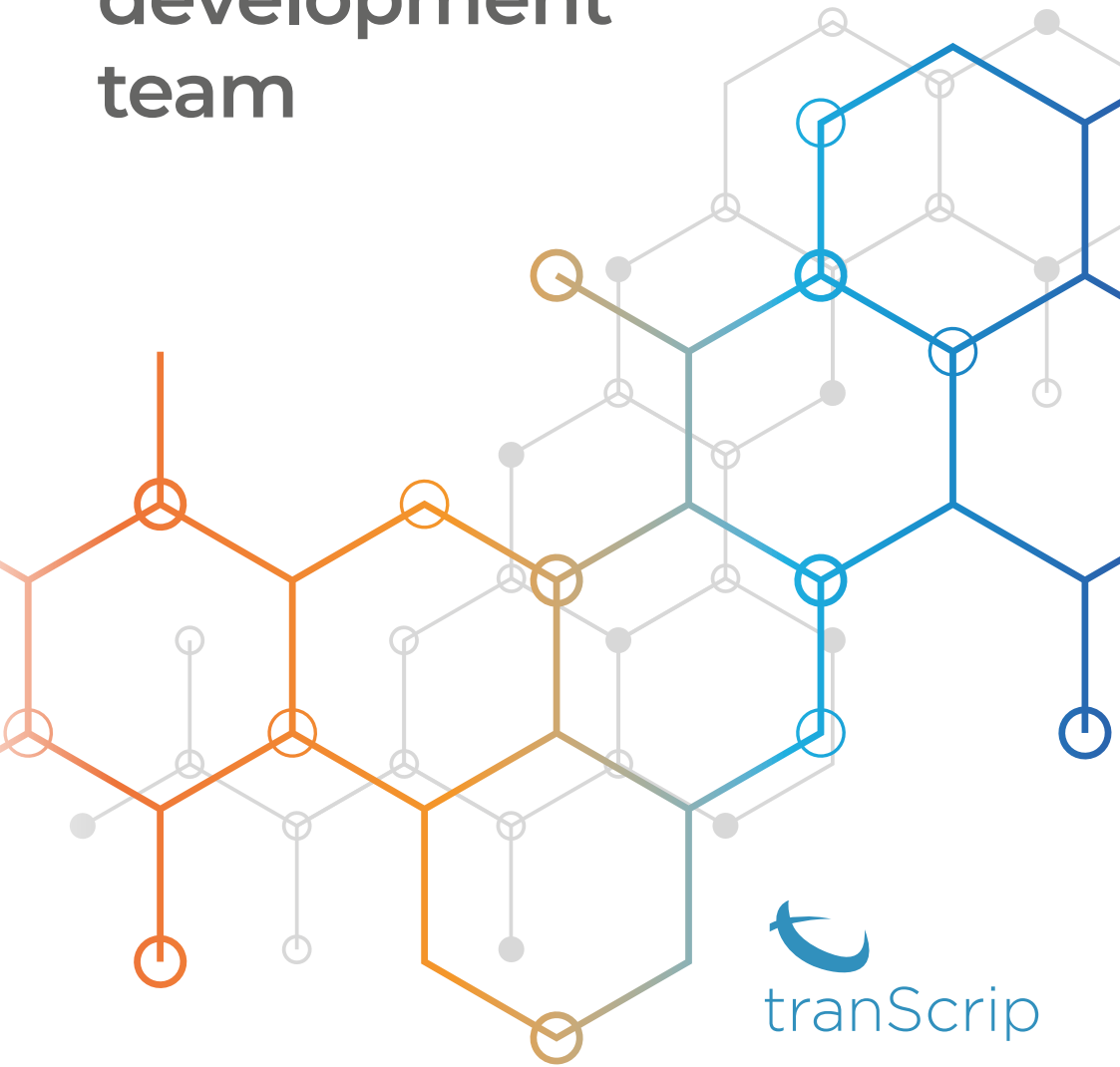
The bespoke clinical and regulatory development team



tranScrip

real regulatory
a tranScrip company

tranScrip and **real regulatory**, now operating as one company, are a leading contract drug development organisation which supports the entire lifecycle of medicines, medical devices and combination products.

REGULATORY

SME Status for EMA fee incentives

Orphan Designations and ATMP Classifications

PIPs/PSPs and Agency meetings

IND, CTA, NDA and MAA preparation and submission

EARLY DEVELOPMENT

Strategy, planning and non-clinical efficacy and safety evaluation

Clin pharm study design and oversight

PK/PD modelling and assessment

Formulation development

CLINICAL DEVELOPMENT

Extensive therapeutic area knowledge

Selection and oversight of CROs

Complete medical and clinical operations support

Drug safety and risk management planning

MEDICAL AFFAIRS AND COMMERCIAL

Target Product Profile evaluation

Launch preparation and training

Lifecycle management planning

Strategic commercial assessments

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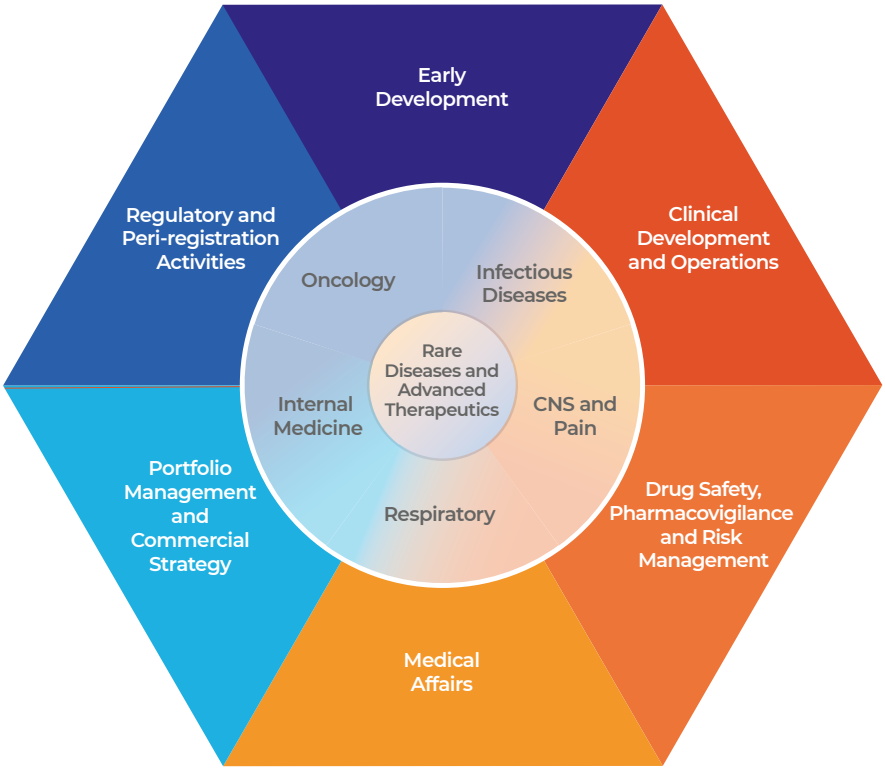
tranScrip

We bring innovative solutions to your drug development needs, providing a true depth of strategy and experience to your projects.

From early development through to registration and post licencing, we deliver both strategic leadership and operational execution, covering clinical, regulatory, drug safety and commercial elements. Our teams of physicians, scientists and regulatory experts, assist clients in selecting the most promising route to market.

Over the last two decades, tranScrip and real regulatory have supported more than 500 clients globally. We have been integral to many development programmes and regulatory submissions, bringing products to market each year across a wide range of therapeutic areas.

You get to determine the elements of our team that you need



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