



tranScrip
**Regulatory Affairs for
Human Medicines**

**Place your regulatory
approval in safe hands**

Visit transcrip-group.com

Your Integrated Product
Development Partner

tranScrip is a leading contract drug development organisation providing strategic expertise and operational support across the entire lifecycle of medicines, medical devices and combination products.

Our Experts



- We are a multi-skilled team of proven experts in regulatory affairs. We excel as a regulatory team alone or alongside our colleagues within the tranScrip team as a multi-functional delivery team
- We provide strategic input & operational delivery for medicinal products over the entire product lifecycle with experience in mitigating against costly delays each step of the way
- Our certified ISO 9001:2015 Quality System underpins a quality culture providing consistency of project deliverables & oversight of your medicines path to commercialisation

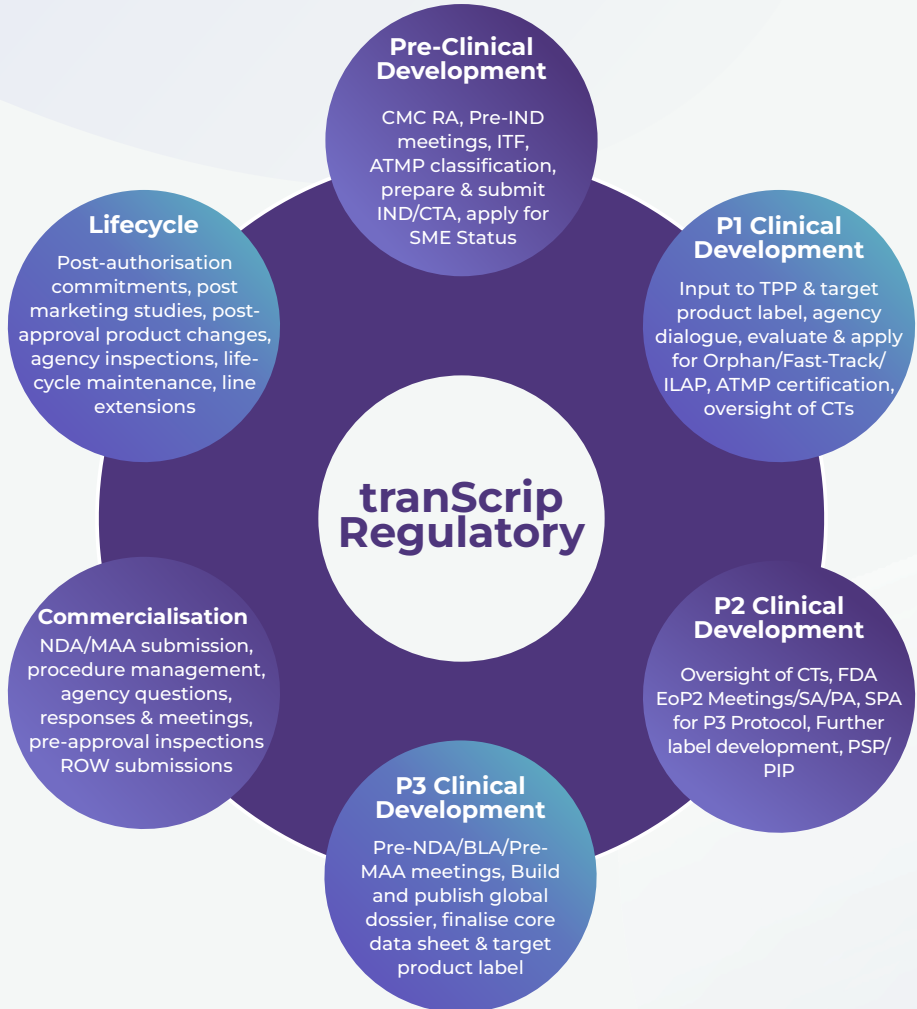
Our Support, Your Deliverable



- Development, licensing & product lifecycle strategy
- Due diligence, gap analysis, technical reviews & consulting
- Planning, driving & leading your agency dialogue & meetings
- Writing, publishing & managing all your agency submissions
- Strategising, development & operational execution of your clinical trials
- Planning, care & management of your product lifecycle needs
- Ensuring your regulatory & quality systems compliance

Our Clients are at the core of everything we do.

Planning, understanding regulatory demands and embracing new regulatory initiatives are essential for optimal drug development programs. Our regulatory experts work independently or alongside our other tranScrip colleagues to provide our clients with efficient support. We deliver timely approvals and support the ever-ongoing development needs of your product throughout its entire lifecycle.



“The service and delivery from these consultants is first class. I wouldn't change a thing.”

- Regulatory Director, European SME

“Thanks to all again for performing such excellent work & in such a professional manner.”

- Associate Director of Regulatory Affairs,
US based speciality pharmaceutical company

Our Value to your projects

- Benefit from tranScrip's significant collective expertise in drug development and study delivery
- De-risk the pathway to smooth the way to commercial success
- Gain rapid access to a highly adaptable, skilled, cross-functional team when you need it
- Maintain consistency along the development journey using an extended team on your side
- Optimise your internal FTE resources, and reduce overheads, internal processes and administrative need



For more info, visit us at:
transcrip-group.com

Or drop us an email:
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