

# Case Study



## Successful Full Team Support for Antifungal MAA-NDA and Beyond

### Challenge

A biotech licensor and its big pharma licensee faced major challenges in overseeing clinical trials for systemic fungal diseases:

#### Clinical Oversight of Systemic Fungal Disease:

- Their teams were short on members and lacked expertise in mycology.

#### MAA/NDA Support:

- There was a need for robust support for Marketing Authorisation Application (MAA) and New Drug Application (NDA) processes. This included preparing documentation, overseeing clinical trials, and ensuring regulatory compliance.

#### Medical Affairs Support:

- The launch teams required comprehensive training in Pharmacovigilance (PV) and medical information. This necessitated a skilled medical affairs team capable of delivering this training across multiple geographic locations.

#### Subsequent Licensing:

- Licensing the antifungal drug to additional territories brought new challenges, requiring further regulatory support to meet the varied demands of different regions and regulatory bodies.

### Solution

To address these challenges, tranScript assembled a bespoke team of experts. Our teams oversaw pivotal confirmatory trials, meticulously prepared and delivered the NDA and MAA submissions, provided comprehensive medical affairs training and ensured smooth global regulatory deployment.

#### Formation of a Specialised NDA Team:

- tranScript assembled a team comprising infectious disease (ID) specialised pharmaceutical physicians, microbiologists, regulatory, medical writers and a project manager.
- The team oversaw confirmatory trials and meticulously prepared and delivered the NDA and MAA.

#### Medical Affairs Support for Training:

- Provided a dedicated medical affairs team to deliver training sessions across Europe.
- The training covered sales techniques, pharmacovigilance and comprehensive medical information.
- Training sessions were conducted in multiple geographic locations to ensure all teams were well-prepared for the launch.



### Global Regulatory Rollout Support:

- Delivered regulatory support for the global rollout to the second big pharma licensee.
- Ensured all documentation and processes met the diverse regulatory requirements of different territories.
- Facilitated smooth licensing and market entry in various regions by providing tailored regulatory guidance.

### Outcome

The drug's completion of Phase III trials paved the way for its swift licensing in the US, quickly followed by approvals in Europe and worldwide distribution. This success was bolstered by our dedicated team, whose expertise in regulatory and medical affairs ensured seamless integration into global markets, supported by extensive training and unwavering support.

### Successful Phase Three Trials:

- The specialised NDA team ensured the completion of Phase III trials, meeting all clinical and regulatory standards.

### Licensing Achievements:

- The systemic antifungal drug was successfully licensed in the US initially.
- Subsequent licensing in Europe followed, with eventual global distribution and market entry.
- The regulatory and medical affairs support provided ensured that the drug met all regional requirements, facilitating smooth market access.

### Enhanced Team Competence:

- The comprehensive training provided to the sales, PV, and medical affairs teams resulted in a highly knowledgeable and effective launch team.
- The teams were well-equipped to handle inquiries, provide accurate medical information, and ensure patient safety through robust pharmacovigilance practices.

### Conclusion

The importance of specialised team support in successfully navigating the complexities of clinical trials, regulatory compliance and global medical affairs in the pharmaceutical industry is evident.

By leveraging tranScip's expertise and experience in mycology and regulatory processes, the biotech licensor and its big pharma partners were able to bring a critical antifungal drug to market efficiently and effectively.