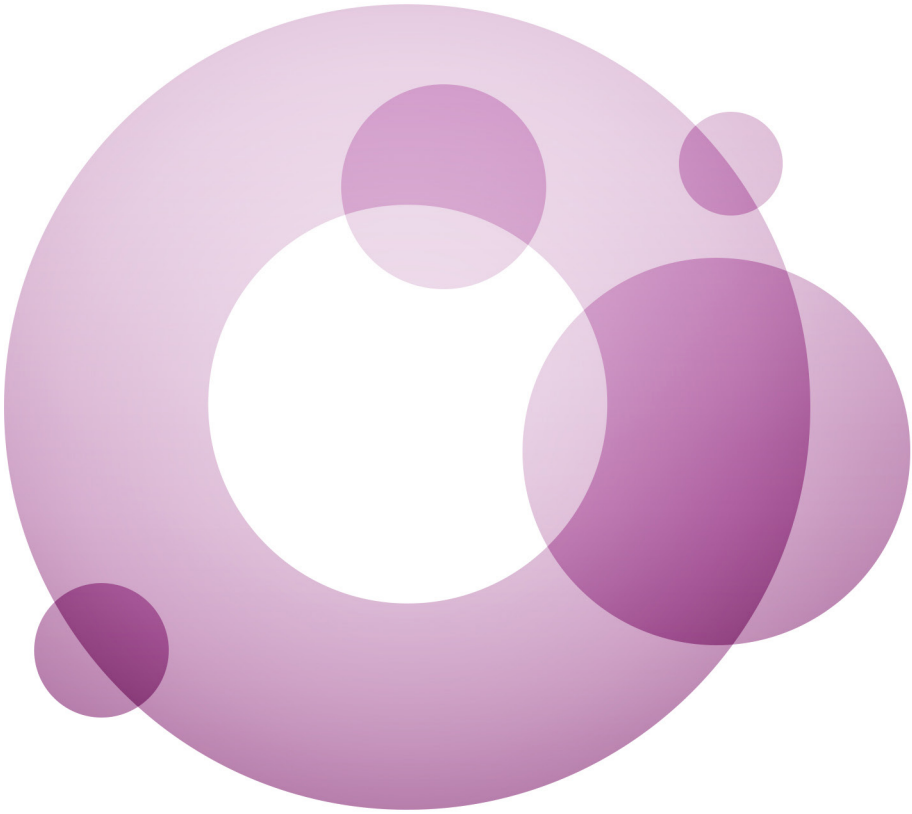
Regulatory advice
The Power of Approval



Pharmetheus
Pharmacometrics Consulting Services

Regulatory advice

Our experience in regulatory strategy makes Pharmetheus a reliable provider of stand-alone regulatory advice. As key advisors to your drug development process, we offer support in creating your regulatory strategy early in the process and all the way through submission.

As a part of our hands-on modeling and simulation projects, we also offer submission ready reports and all our efforts are characterized by traceability and accountability - from data management to report finalization.

With former regulatory assessors (EMA, FDA) on staff, we can support your regulatory interactions across the product life-cycle.

Our services include:

- Advice on the regulatory strategy.
- Assessment of available documentation for regulatory submission (e.g., iPSP/PIP, CTD section 2.7.2, and modeling reports).
- Preparation and attendance at agency meetings (e.g., EOP2, pre-submission and regulatory scientific advice meetings).
- Support in answering questions from regulatory agencies.

In our experience, the structured approach to analysis and reporting developed and adopted by Pharmetheus has greatly facilitated regulatory interactions In fact, the structured way of reporting developed at Pharmetheus has rendered positive attention from regulatory agencies.