Case Study

Data Science long-term support to a global submission dossier

Challenge

Support in clinical statistics and pharmacokinetics in support of a global submission dossier

- Statistical and pharmacokinetic input in the each application dossier (e.g. modules 2.7.2 and 5 for FDA)
- Need to summarize heterogeneous information from different sources and providers used during the clinical development
- Quick feed-back including new analyses to support the answers to the questions raised by the different regulatory agencies

Solution

One dedicated team of data scientists

- Composition of a team of data scientists of different levels and of programmers to be able to react quickly on any type of regulatory request
- Close relationship with the sponsor regulatory and clinical/medical people

Outcome

Contribution to the marketing authorization obtained in several regions/countries

- All tasks delivered within defined time frame
- Statistical and pharmacokinetic answers provided and accepted by the different regulatory authorities
- Marketing authorization granted by EMA, FDA, Health Canada (several other regions/countries ongoing or pending)