Post-regulatory support to an EMA clinical submission

Challenge

Support required to respond to EMA feedback on study results

- Several concerns raised by EMA on the design of the pivotal study for the registration of a generic drug diffusion system (DDS)

Solution

Proposed and performed a fully revised analysis of the primary end-point of the study

- Developed a rationale to justify the acceptability of the positive results obtained with the newly proposed analysis, despite the flaws of the study design
- Proposed and completed additional analyses to support further the similarity of the new DDS with its EU reference

Outcome

Based on improved analysis, the dossier was finally approved in the EU

- All tasks delivered within defined time frame