NDA pharmapprove

Submission Support Case Study

Global Gap Analysis

Challenges

- Assess gaps in foreign clinical and preclinical data to meet US and EU agency requirements for two different but related indications
- Multiple interactions with FDA, some EU National advice but no EMA Scientific Advice
- Multi-national team headquartered in Asia
- Given phase 3 program nearing completion, focus on addressing issues critical to approvability

Our Approach

- Conduct gap analysis of the preclinical data, clinical data and phase 3 study designs versus US and EU requirements and expectations for the two indications
- Ascertain US and EU clinical requirements and required comparators
- Work through strategies to address each gap with additional data, analyses or developing a rationale/argument

Outcome

- Identified need for preclinical study not previously considered
- Aligned expectations regarding global clinical trial designs
- Lowered program risk and potential for costly delays and future course-correction by working on mitigation strategies prior to submission writing
- Plans to continue working with Company to carry forward strategic messaging to address gaps in application documents and pre-filing interactions with global regulators

Global, Streamlined Support

- ✓ One contract to cover all activities
- ✓ One joint project manager, principal lead
- ✓ Kick-off meeting to define plan, roles and responsibilities and align the team
- ✓ European & US experience and guidelines reflected
- ✓ Access to top experts in both regions
- ✓ Scientific, Regulatory, HTA and Communications professionals
- ✓ Consolidated assessment and joint meetings for efficient workstreams

"We needed external expertise to review and highlight gaps/risks in the program, but more so to focus the team on mitigation strategies well before the Applications."

For more information and casestudies, visit: **ndareg.com/pharmapprove**

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