NDA pharmapprove

Clinical Development Program Case Study

Consolidated US/EU Phase 3 Program

Challenges

- Develop harmonized phase 3 program for new indication to comply with US and EU requirements
- Need for consolidated external expert advice
- Anticipate perspectives of both US and EU regulatory bodies
- Strategic regulatory and clinical advice needed regarding gaps and opportunities to facilitate approval

Our Approach

- Assessed regulatory landscape in the US and EU
- Reviewed available clinical pharmacology and early clinical trial data in the concerned indication
- Held a Challenge Panel to lead a diverse group of experts through a complex development discussion to gain consensus on key ideas
- Provided complete logistics coordination for meeting with client and experts from all companies and regions

Outcome

- Integrated clinical development program to support regulatory submissions in US and EU
- Identified potential challenges for NDA/MAA
- Invaluable feedback from challenge panel of US and EU experts
- Consolidated report
- Solutions-driven action plan for regulatory dialogue

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

Successful global phase 3 development program to meet US and EU regulatory needs

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

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