## **Regulatory Approvals for Multi-Countries**

**Case Study:** Medical device company in the US with a large product portfolio, looking to launch new audiometry device in Asia







X months?

8 months





Results



Product launch of a new product from a recently-acquired company, prefer to be agnostic to the distributors, and needs flexibility over the number of distributors per country - been challenging to deal and negotiate with various distributors

Very few companies have the physical resources to provide multi-country product launch capabilities including regulatory, logistics, post market care, and can remain neutral to the financials

Connected with Access-2-Healthcare through a referral, learns of the capability of the multicountry physical entities Allowed the medical device company to understand our physical infrastructure, assigned resources for support in regulatory and logistics, executed simultaneously



Provided authorized representative services + executed activities to gain regulatory approvals in these countries

Managed the post market surveillance activities and provided importation support

Product launched in 5 countries

Other examples: Neurology software-as-a-medical device launched in Thailand, Philippines

