

Case 2: An illustration of a successful POC study conducted in India



Indication : Overactive Bladder (OAB)

Full Scope Study

European Sponsor

- *Phase II (POC) Study*
- *“First in Patients” Study*

Sponsor Requirement

- ***100 Patients to be screened***
- ***77 Patients to be randomized***
- ***63 Patients to be completed***

- **No. of sites planned : 10**
- **Recruitment timelines : 5 months**

Case 2: Outcome surpassed expectations even with the timelines reduced by 50%

	Sponsor's Expectations	Actuals
Number of sites	10	9
Recruitment timelines	5 Months	2.5 Months*
Number of patients screened	100	130
Number of patients randomized	77	73
Number of patients completed	63	66

- Recruitment timelines condensed to 2.5 months due to early study medication expiry*
- 100% Achievement of timelines, completed patients & budgets.