

# What CMOs Need to Know About Running Clinical Trials in South Korea



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## Developing a Global Clinical Trial Strategy

**CMO360°**  
Chief Medical Officer Summit

**LEARN – SOME PROS AND CONS  
OF RUNNING CLINICAL TRIALS IN  
SOUTH KOREA AND  
REGULATORY AND OPERATIONS  
LESSONS LEARNED**



# QLARIS: A SMALL 8 PERSON BIOTECH TEAM

- IS DEVELOPING A TOPICAL IOP LOWERING EYE DROP
- QLARIS WAS INTERESTED IN STUDYING NORMAL TENSION GLAUCOMA (NTG)
- MAJORITY OF GLAUCOMA PATIENTS IN ASIA HAVE NTG
- SELECTED LEADING KOLS AND PIS IN SOUTH KOREA



# ENGAGED CROS FOR CLINICAL STUDY

- STARTED WITH LARGER CROS – DISAPPOINTED
- SELECTED CROS WITH GLOBAL ASIA EXPERIENCE & EXPERTISE
- BID DEFENSE – A TEAM
- SIGN A CONTRACT - PROJECT MANAGER CHANGE OVER WEEKLY
- C TEAM AT BEST – TIMELINES SLIPPED



# COULD WE DO THIS IN HOUSE?

- ENGAGE WITH OUR LOCAL US CENTRIC OPHTHALMOLOGY CRO
- CONTRACT WITH A SOUTH KOREA IN COUNTRY CRO
- SUPPLY CTM & SHIP WITH STORAGE DEPO IN SK
- WHO WILL HOLD THE IND?



# OPERATIONALIZE



## PROS FOR PRN

- PRN HAD OPHTHALMOLOGY EXPERTISE
- PRN KNEW QLARIS AND THE TEAM
- DP FILL AND FINISH WAS CONDUCTED IN US
- LABELING IN US WITH KOREAN LANGUAGE

## PROS FOR SYNEX

- SYNEX HAD SK EXPERTISE
- SYNEX KNEW THE KOLS/ SITES
- SYNEX KNEW THE CULTURE
- **SYNEX KNEW MFDS**
- SHIPMENT AND STORAGE IN SK

# CHALLENGES



## OBVIOUS & NOT SO OBVIOUS

- TIME ZONES
- COMMUNICATIONS – “LOST IN TRANSLATION”
- DOCUMENTATION TRANSLATION
- EXTENSIVE AE COLLECTION – EVEN WITH EXTENSIVE PRIOR CLINICAL DATA
- CLINICAL SET UP WAS DIFFERENT – 9 AM START (BCVA CHART)
- KOREAN VACATIONS AND HOLIDAYS

## NOT AT ALL OBVIOUS

- CULTURE – NICETY
- COMPARATOR WAS NOT APPROVED IN KOREA (SINGLE USE PRES FREE TIMOLOL)
- MFDS WANTED CHRONIC AND EMBRYOFETAL TOX FOR DOSING > 2 WEEKS
- PREGNANCY TESTS AND CONTRACEPTION FOR ALL WOMEN AND MEN
- 4 WEEKS POST LAST VISIT FOR AES

# LEARNINGS

- YOU MAY NOT KNOW WHAT YOU DON'T KNOW
- ENGAGE WITH A LOCAL CRO IF POSSIBLE
- TRAVEL TO THE COUNTRY AND MEET THE PIS AND SITES
- UNDERSTAND THE CULTURE AND PREFERRED WAY OF COMMUNICATION
- EXPECT HICCUPS WITH A DIFFERENT WAY OF DOING THINGS
- SOME REGULATORY BODIES – VERY RISK AVERSE

**THANK YOU**