



**IMDRF**

International Medical  
Device Regulators Forum

# **RPS Table of Contents Pilot Survey Results**



# Presentation Outline

- Survey summary
- Survey questions and responses
- General comments

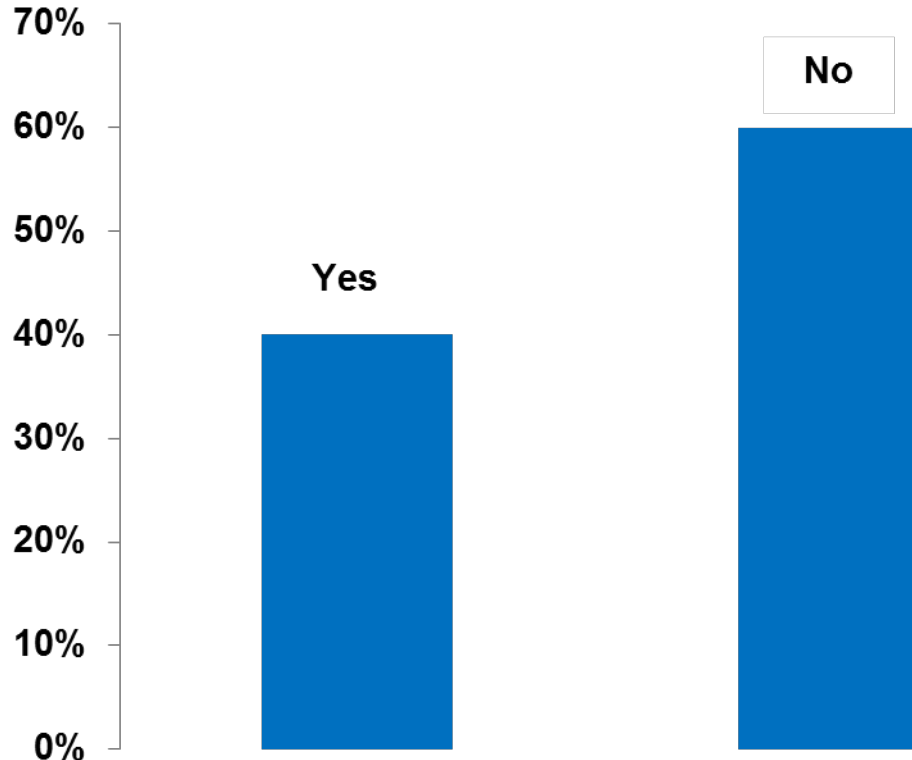


## Survey Summary

- Consisted of 10 questions (with subparts)
- Distributed to GMTA and DITTA members
- Coordinated disclosure
- Open for 4 weeks
- Number of respondents = 70

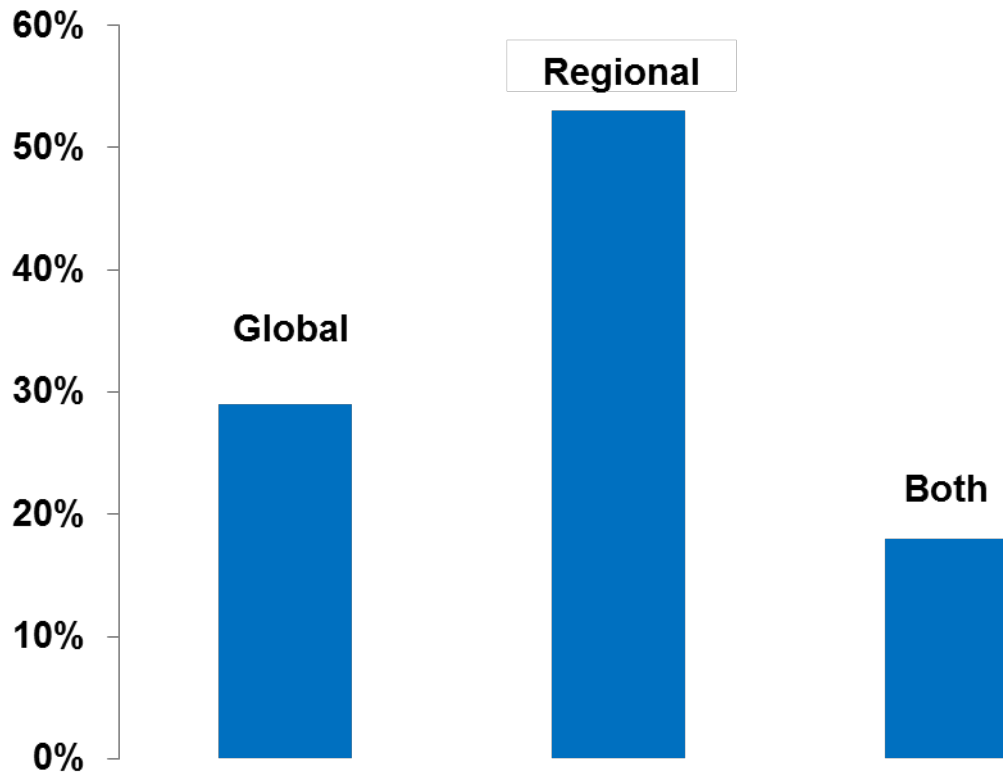


# Did your company participate in the TOC pilot?





# In which pilot did your company participate?



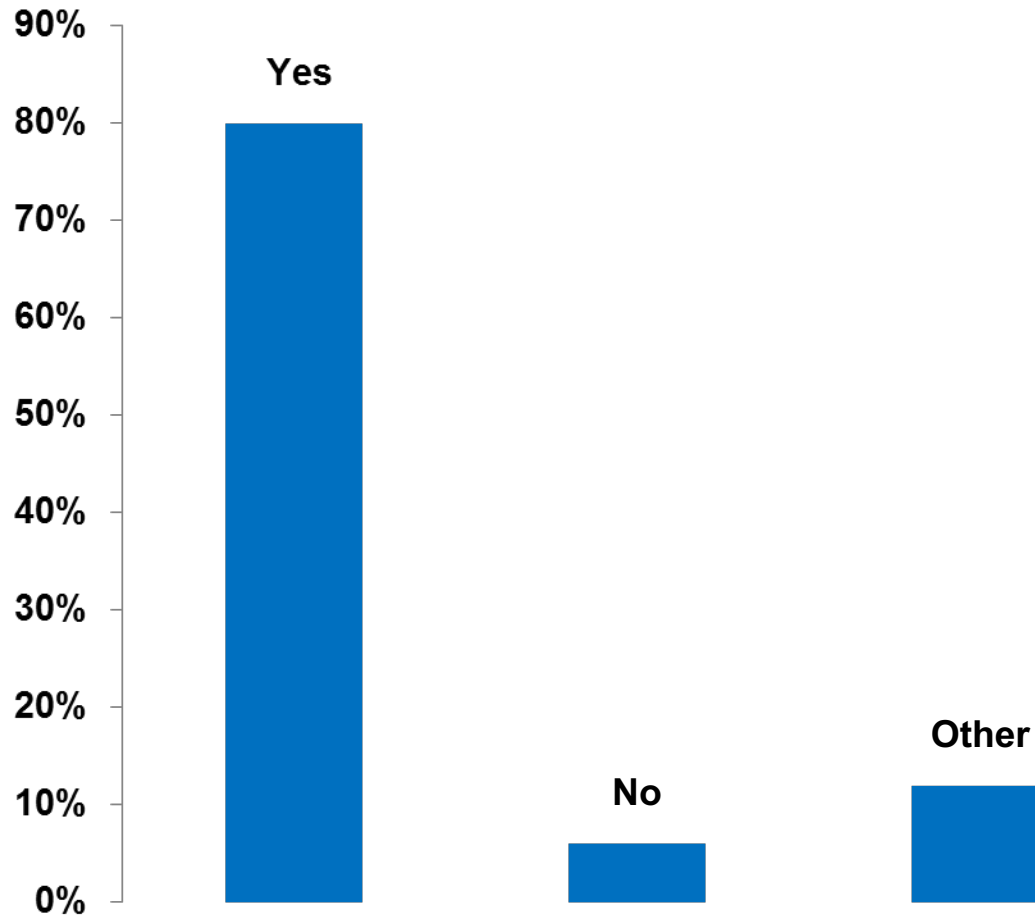


# Why did your company participate?

Response	Number
To understand/evaluate TOC structure	7
Contribute to harmonization efforts	3
Participant in IMDRF RPS Working Group	2
For registration of new products	2



# Was participation of value?





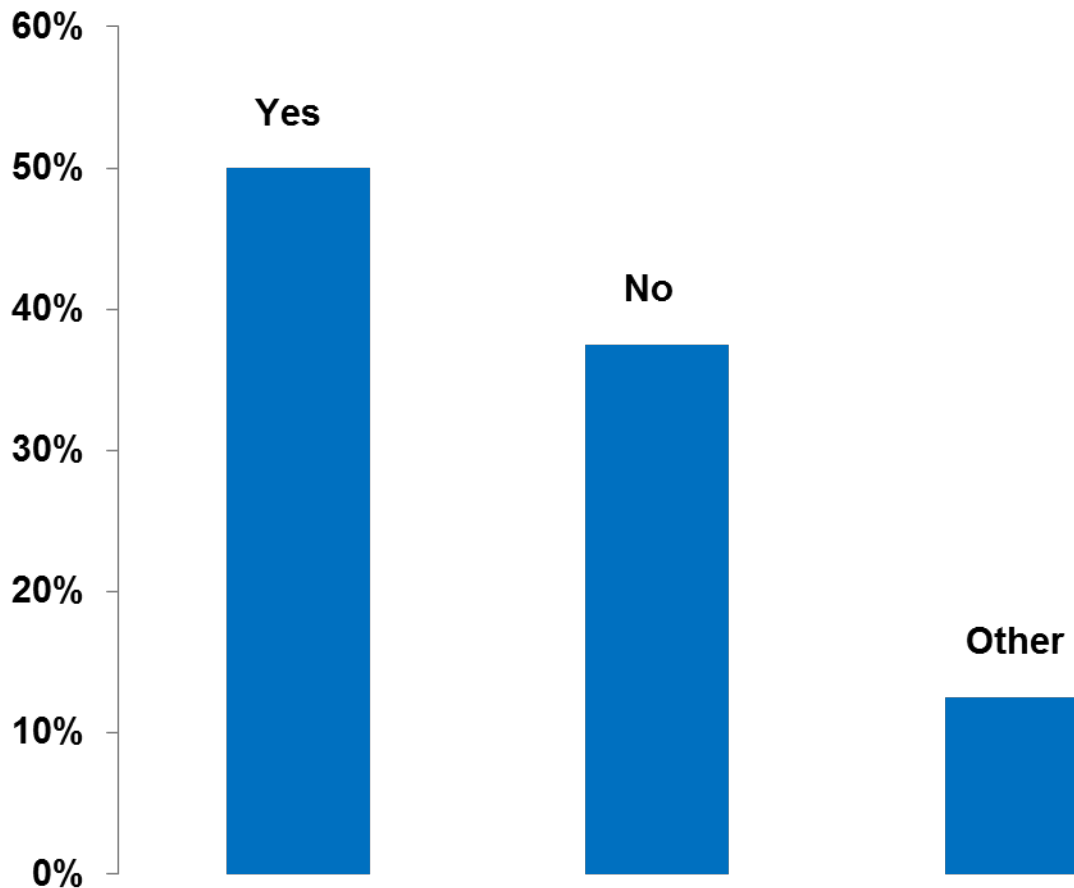
## For which countries did you submit?

Country	Number of submissions
Canada	10
Brazil	8
China	3
United States	3
Australia	2





# Have your reviews been completed?





# How long did your review take?

Timeframe	Number of Respondents
4 to 6 months	5
Same as usual	3



## How would you improve the pilot experience?

Response	Number of respondents
More clarity/guidance on requirements	5
Overall good experience	4



# Reasons for not participating in the pilot

<b>Response</b>	<b>Number of respondents</b>
Unaware of pilot	7
Resource constraints	5
Uncertainty regarding timing	2

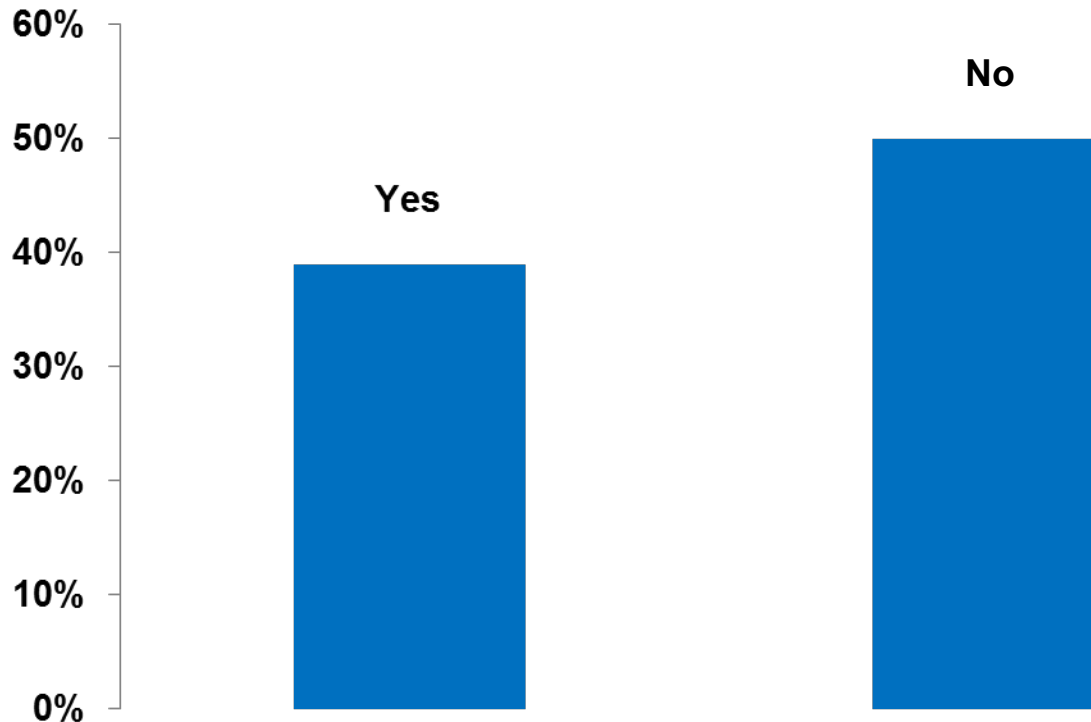


# What would have convinced you to participate?

Response	Number of respondents
Clear benefit/value proposition/faster reviews	8
Nothing would convince me	4

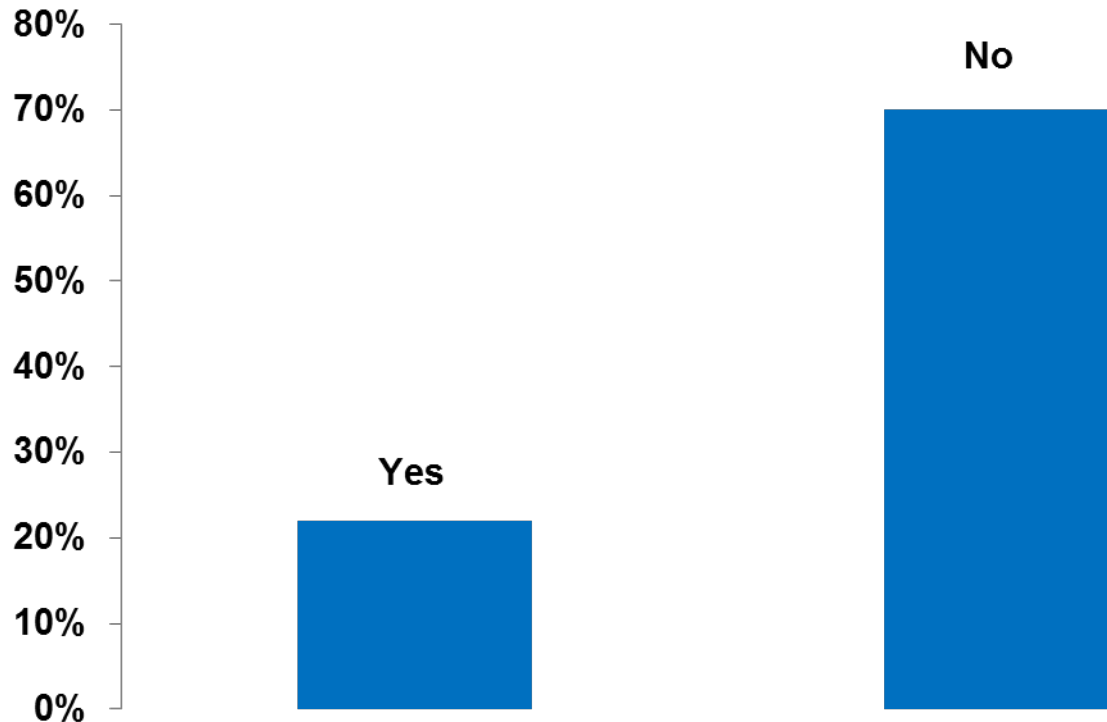


## Do you currently utilize an electronic platform to prepare your submissions?





## Do you currently utilize an electronic submission tool to send your submissions?





## General Comments

- QMS should be harmonized first
- Usefulness depends on regulator participation and adoption
- More information on benefits of program needed
- Should not take longer and cost more
- Less cumbersome process needed





## General Comments

- Granularity of template is helpful—more useful than STED
- Required granularity is redundant
- Transparency on alignment of timelines
- Pilot results reporting would be helpful
- Procedures to update TOC during review needed