The 9th Annual Meeting of ISMPP

Empowering the Medical Publication Community to Advance the Profession

ISMPP International Society for Medical Publication Professionals

View From the Regions

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Faculty

- Julliana Newman, ELS
  - Associate Director Regional Strategic Medical Communications (China, Intercon Asia-Pacific & Japan), Bristol-Myers Squibb
- Ehab Youssief Mahgoub, MD, MSc
  - Senior Regional Medical Director, Emerging Markets, Pfizer Inc
- Michael Platt, ISMPP CMPP™
  - President, MedVal Scientific Information Services, LLC
- Moderator: Aruna Seth, PhD, Scientific Team Lead, UBC-Envision Group, ISMPP CMPP™

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Agenda

- Panel presentations
- Table Talk
- Panel Q&A

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Taking your Data from Global to Market

JULLIANA NEWMAN, ELS, CMPP™
Associate Director, Strategic Medical Communications
China, Intercon (Asia-Pacific) & Japan
Bristol-Myers Squibb

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Disclosure

- Julliana Newman is a full-time employee of Bristol-Myers Squibb.
- She has no other conflicts of interest to disclose.
- The opinions expressed in this presentation are the personal views of the speaker and do not represent the views of Bristol-Myers Squibb.

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Bristol-Myers Squibb's Footprint in Asia-Pac*

The region is divided into 3 markets:

- **China**
- **Japan**
- **Asia-Pac**
  - **Korea**
  - **Taiwan**
  - **Hong Kong**
  - **Thailand**
  - **Singapore**
  - **India**

*We no longer break out emerging markets.

Audience Question

Do you work in an emerging market?

a. Yes

b. No

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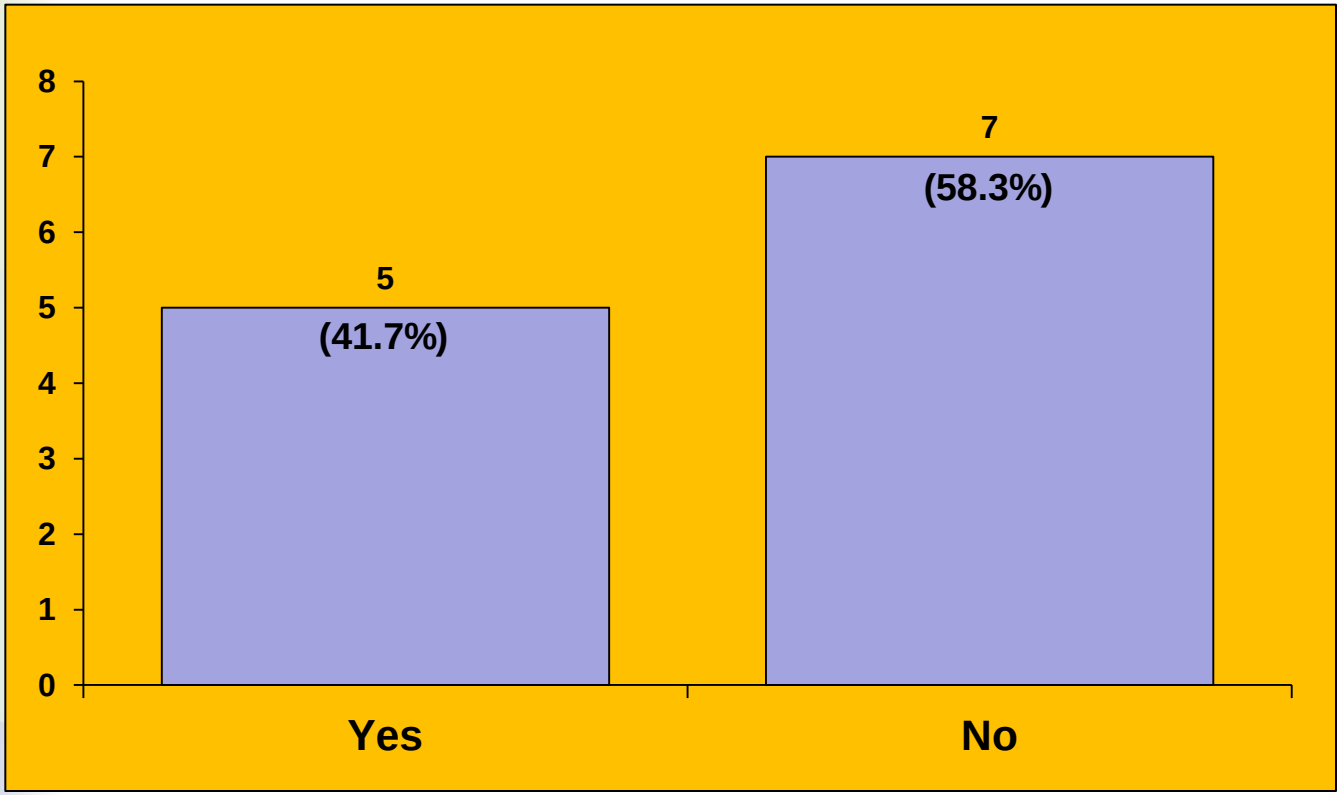
Do You Work in an Emerging Market?



Responses = 12

Audience Question

If YES, where?

a. Asia-Pac

b. Europe

c. South America

d. Africa/Far East

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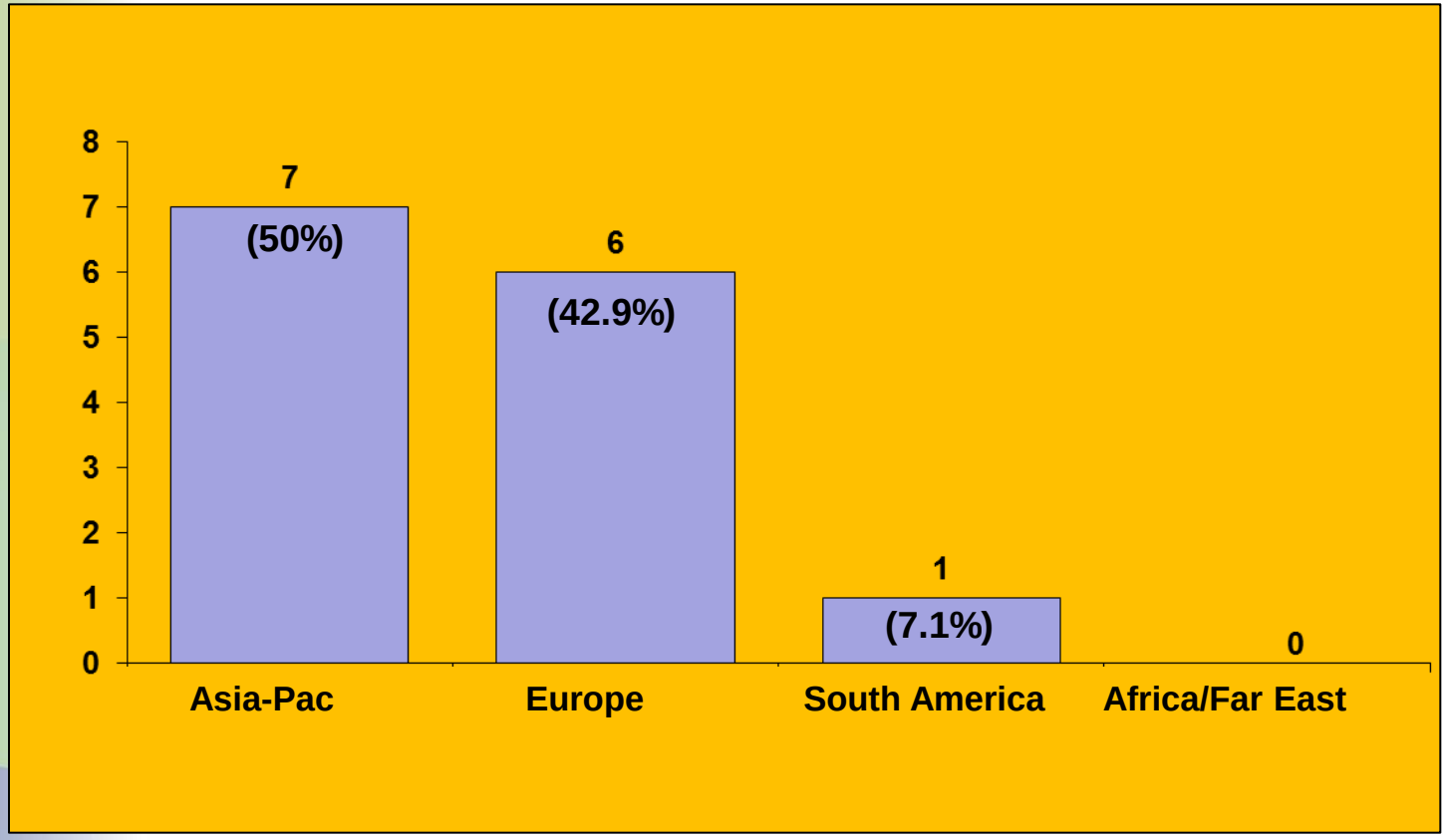
If YES, Where?



Responses = 14

Audience Question

Are your regions/HCPs familiar with GPP2/ICMJE guidelines?

a. Yes

b. No

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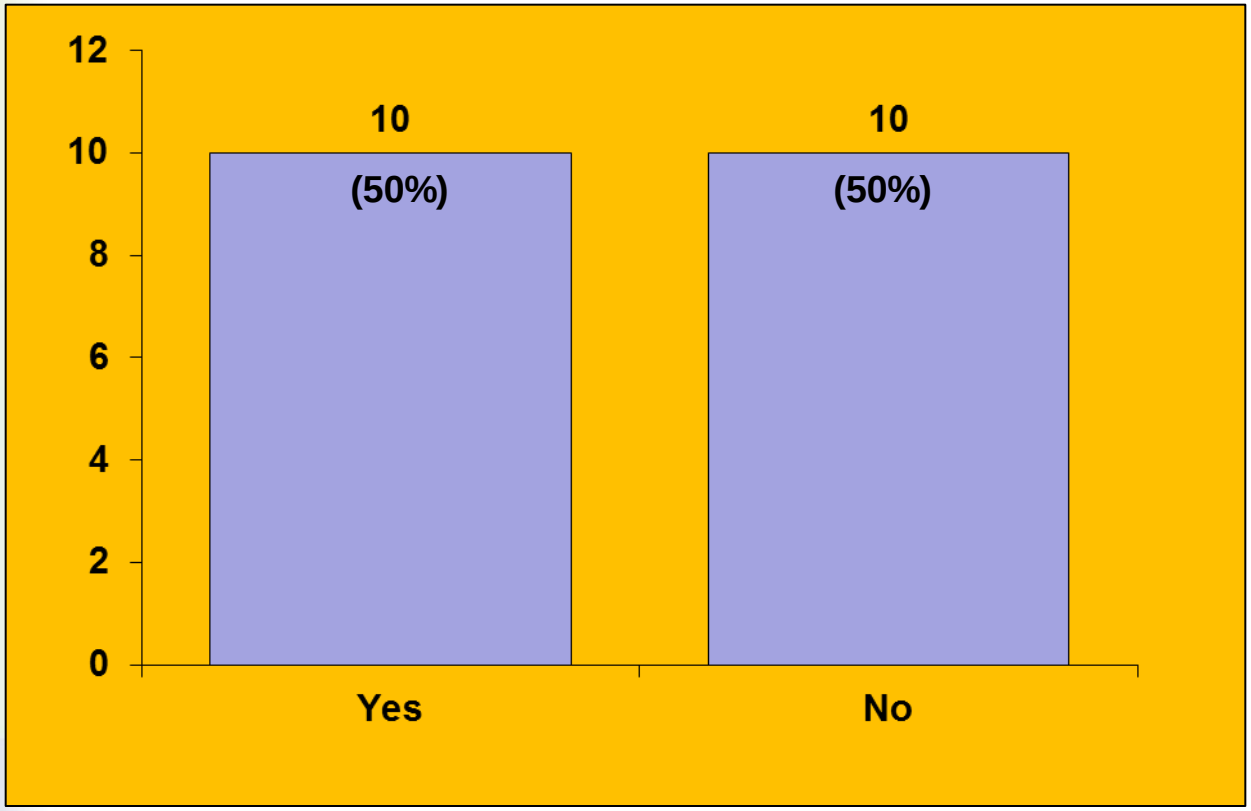
Are Your Regions/HCPs Familiar With GPP2/ICMJE Guidelines?



Responses = 20

Audience Question

Does the product lifecycle figure into your local publications plans?

a. Yes

b. No

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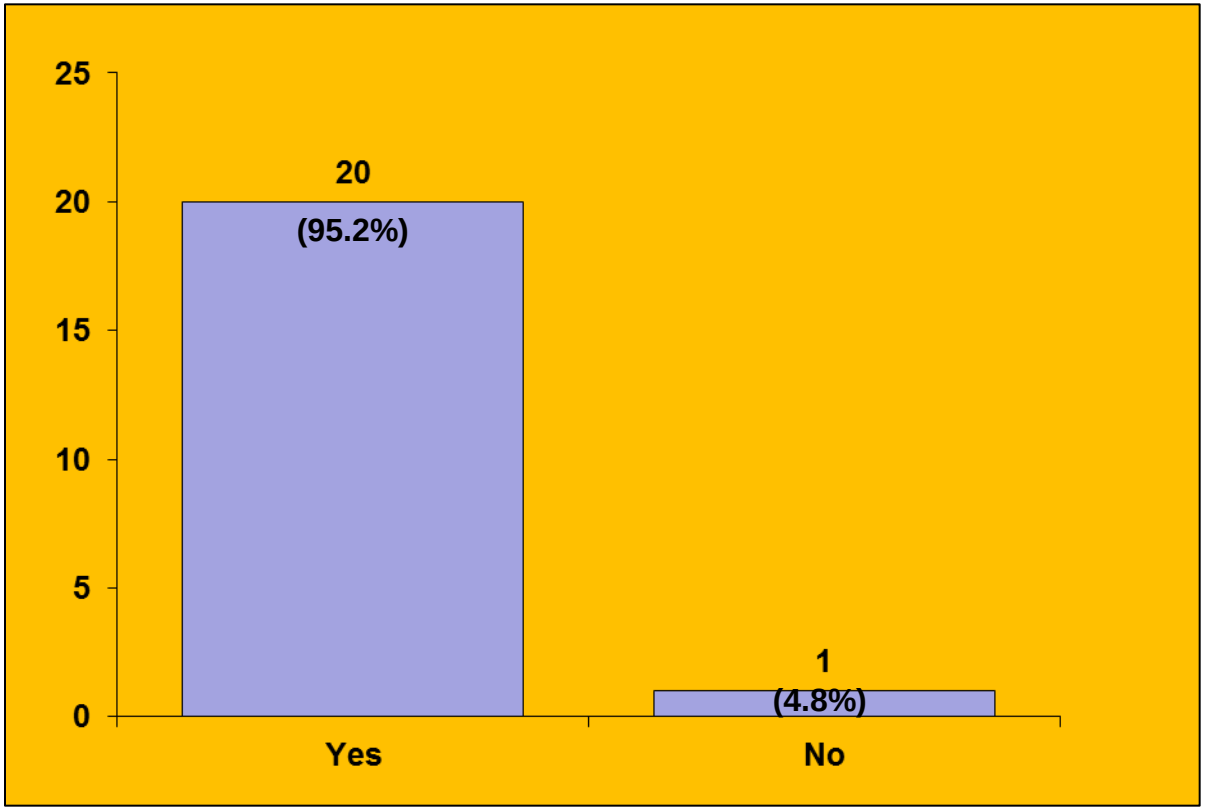
Does the Product Lifecycle Figure into Your Local Publications Plans?



Responses = 21

Audience Question

Do you have an encore policy currently in place for your emerging markets?

a. Yes

b. No

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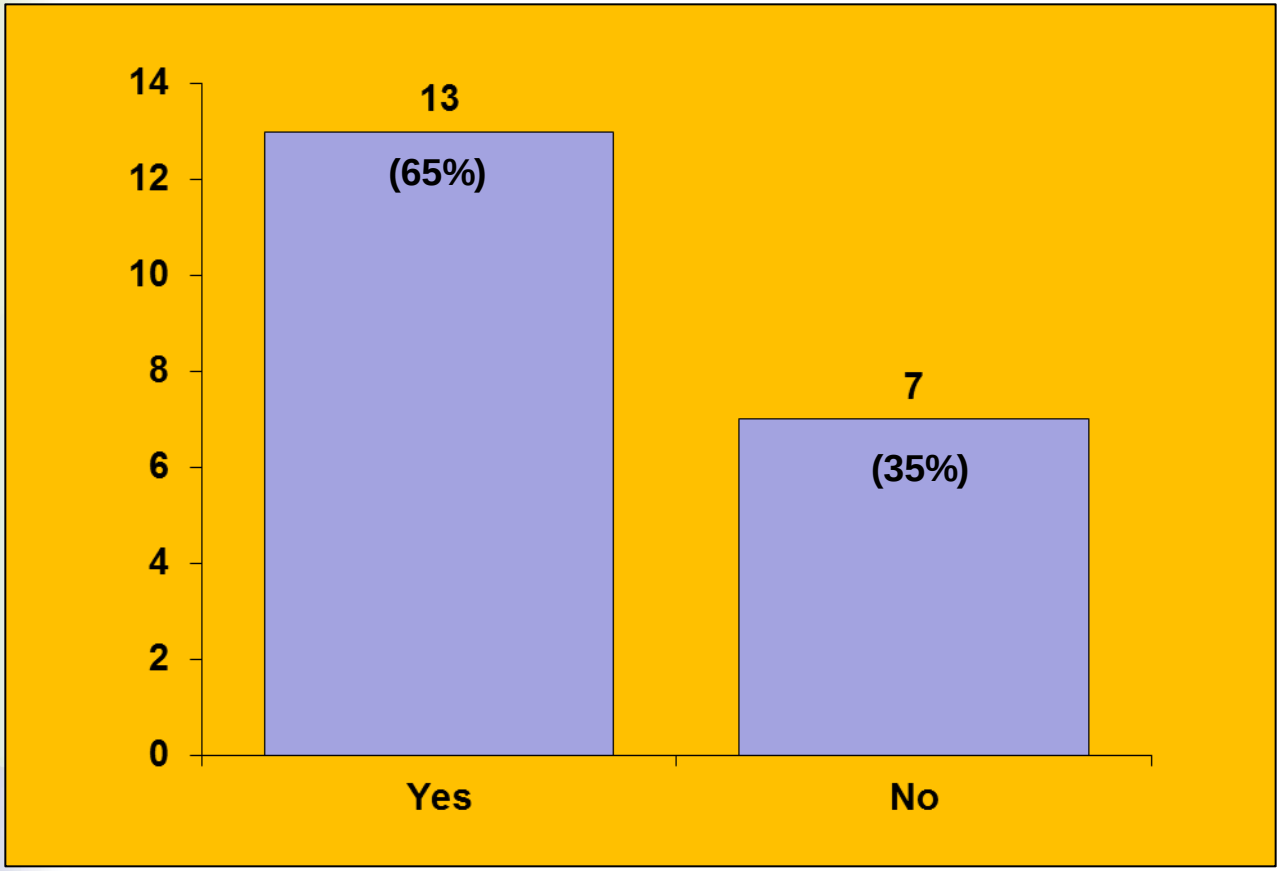
Do You Have an Encore Policy Currently in Place for Your Emerging Markets?



Responses = 20

Audience Question

Have you experienced any issues obtaining copyright permissions related to encores?

a. Yes

b. No

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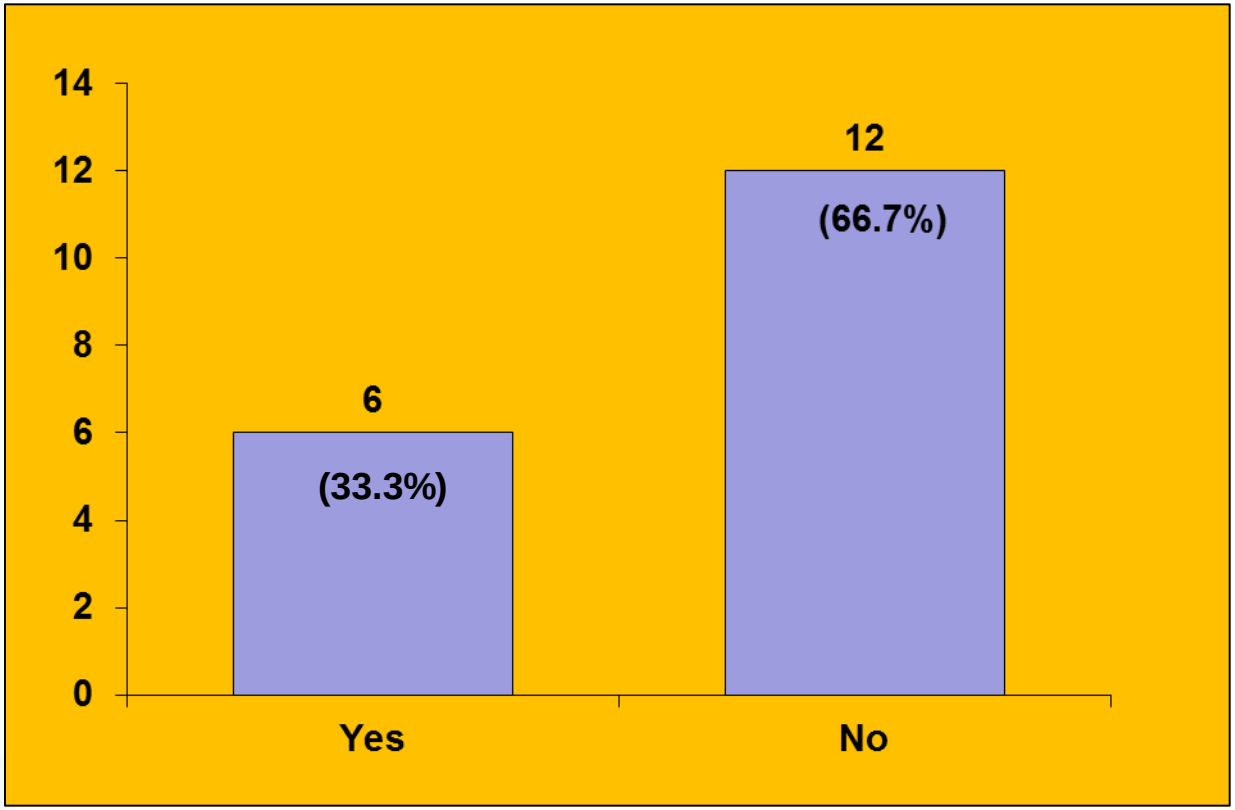
Have You Experienced any Issues Obtaining Copyright Permissions Related to Encores?



Responses = 18

Taking your Data from Global to Market

Challenges may include

- Product lifecycle management
- Publication planning challenges
- Local language (translation accuracy)
- Local congress requirements (1st author vs. presenter)
- Non-English speaking HCPs
- Lack of familiarity at a local level with international publication guidelines
  - ICMJE
  - GPP guidelines
- Compliance with USA standards/Corporate SOPs
  - Sunshine Act
  - FCP Act
- **Copyright**

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To Encore or Not to Encore: That is the Question

What Is an Encore?

Reproduction of a publication (abstract/poster/oral presentation) that was previously published/ presented at a major congress

Why Do We Encore?

HCPs in the local markets may be unable to attend global congresses but are interested in learning about the latest developments in their related therapeutic areas

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Practical Encore Guidelines

- An encore presentati[illegible] shoul[illegible] be done if there is a legi[illegible]mate need [illegible] audien[illegible]e that is distinct f[illegible]e pri[illegible] of [illegible] original presenta[illegible]
- Enc[illegible]”
- A[illegible] must [illegible]e to the en[illegible]

Copyright permission must be obtained from original copyright holder

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Let's Focus on Copyright for the Moment

Challenges

- Determine "Who owns the copyright"? The "six million dollar" question!
- Identify the original publisher & request permission to encore
- Provide all required information (this may vary)
- Receive permission & notification of any charges
- Ensure timely payment process is completed at a local level

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Obtaining Copyright Permission: A Case Study

Start: 2nd Nov 2012 – End: 11th Jan 2013

To: Ganesan, Balaji; Farrelly, Marese - Melbourne
Cc: Newman, Julie
Subject: RE: wiley copyright [redacted]
Date: Friday, 11 January 2013 9:55:51 PM
Attachments: image002.png
image003.png

11th Jan

Dear Balaji,

Thank you for your email.

Please find our gratis gr[illegible] of the abstract at [illegible]

Pe[illegible] to the usual acknowledgements (au[illegible] ourselves as publisher).

Any th[illegible] expressly excluded from this permission. If any of the material you wish to [illegible] within our work with credit to another source, authorisation from that source must be obtained.

This permission does not include the right to grant others permission to photocopy or otherwise reproduce this material except for versions made by non-profit organisations for use by the blind, visually impaired and other persons with print disabilities (VIPs).

The steps required to obtain copyright permission for an Encore

1. Identify the original publisher & the contact person
2. Email sent with a summary of the request
3. After two weeks and a gentle reminder, we received the first response with request for additional information
4. After a month (with several reminders), response received with more questions
5. After another month (with more reminders again), response received with more questions again
6. Finally after more than 2 months of trying, we received the COPYRIGHT PERMISSION

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Lessons to be Learned

- Copyright is an essential component of the encore process
- Some helpful tips:
  - Do not underestimate the time it can take to obtain copyright permission
  - Be persistent
  - Be diligent and document the entire process
- And most of all, don’t give up.....

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The Journey to Good Publication Practice

The way to good publication practice is like climbing the Great Wall. It is a long and winding road, but the rewards of seeing your work published at the end are worth the effort. (photograph© 2013 Christopher Meder/123RF.com)

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Regional Authors & Journals selection in Emerging Markets: Challenges & Opportunities

Ehab Youssief Mahgoub, MD, MSc

Senior Regional Medical Director

Pfizer Emerging Markets

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Disclaimer

- Full time employee, Pfizer Inc (Emerging Markets) 2002-to date
- No other conflicts of interest to disclose
- The opinions expressed in this presentation are the personal views of the speaker and do not represent the views of Pfizer.

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Audience Question

What would be your annual budget if you are working in the Emerging Markets publications?

a. <$100K

b. $101K – 500K

c. $500K – 1M

d. >1$M

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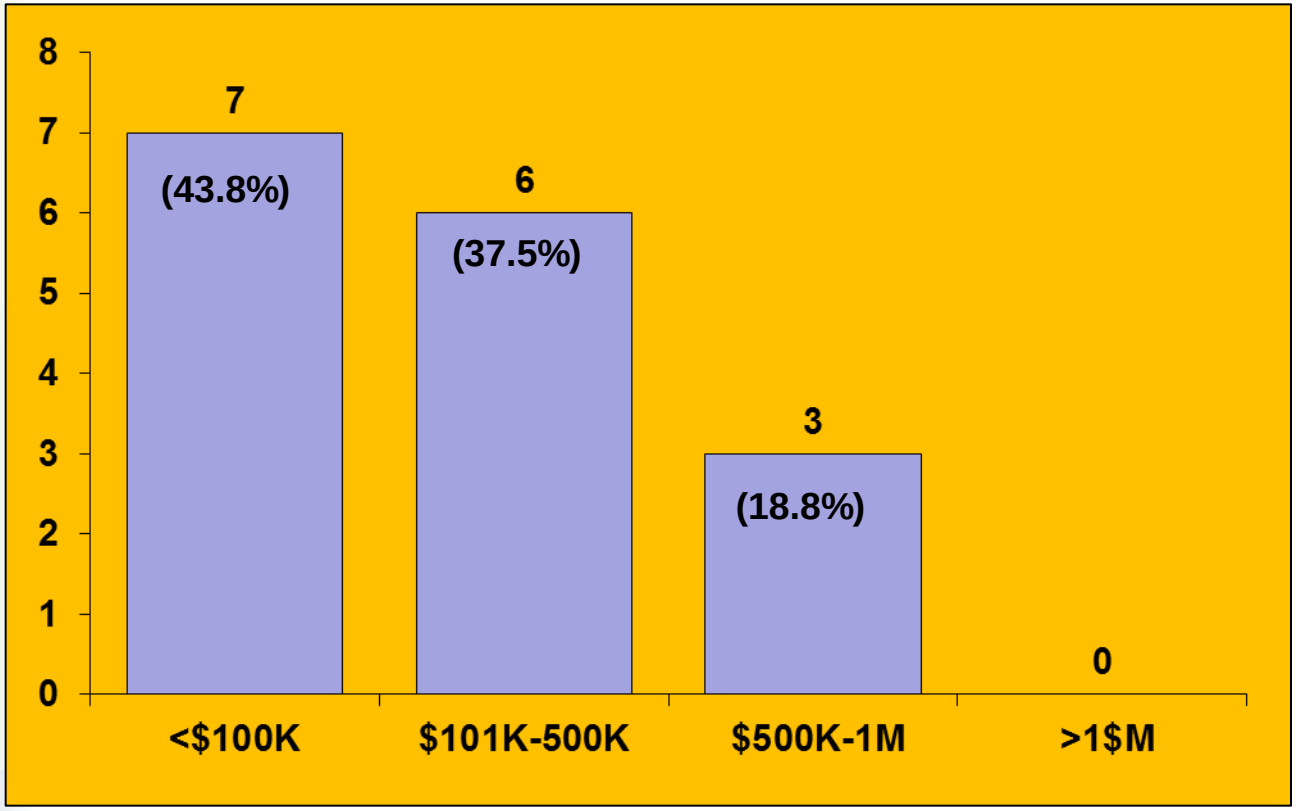
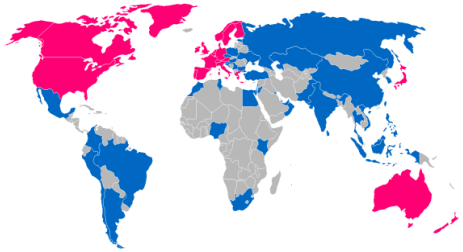
What Would be Your Annual Budget if You are Working in Emerging Markets Publications?



Responses = 16

Regional Authors: Challenges?



- **Local/regional authors:**
  - Cultural/local practices regarding working with local authors - ensuring compliance with ICMJE guidelines
  - Lack of evaluation of subject matter
  - Lack of awareness regarding the principles of journals evaluation and selections
  - Tendency towards regional/local sub population analyses (has an extensive impact on medical, clinical and statistical personnel time and workload)
  - Local authors & tendency towards review articles
  - Tendency to target top international journals (low acceptance rate)

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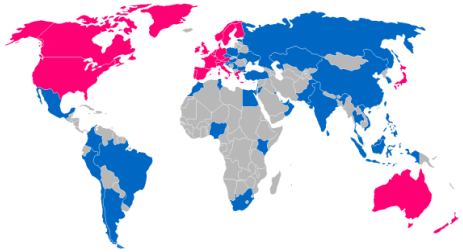

Journals selection: Challenges?

- **Local/regional journals:**
  - Low impact factor
  - Limited audience & reach
  - Not indexed in Pubmed
  - No open access availability
  - Local languages
  - Lack of effective communication with local/regional journals
  - No clear time lines (submission to publication)
  - Manuscript publication efforts incur significant monetary costs (agency support and journal fees)

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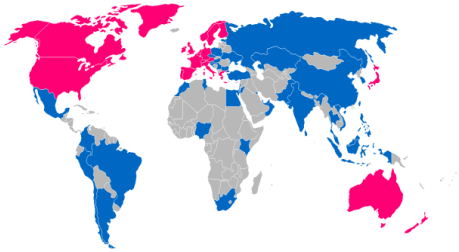
Regional Authors & Journal Selection: Opportunities



- **Internally:**
  - Identify key scientific “region-specific” questions of medical interest
  - Collaboration between local/regional & global teams
  - Collaborate with the Bio Statistical Open House (BSOH) to establish concept, generate data and discuss interpretation
- **Externally:**
  - Regional authors will champion the data generation
  - **Education** regarding authorship criteria
  - **Education** regarding evaluation of subject matter
  - **Education** regarding Journals specifications & evaluation tools
  - **Education** regarding successful strategies for journal selection
  - Identify regional or local journals

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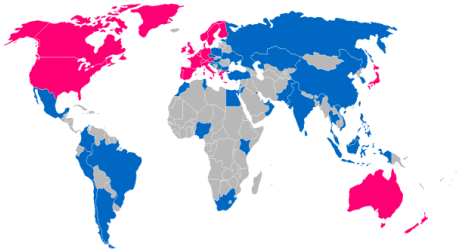
Regional Authors & Journals Selection Advantages



- Disseminate scientific information which is specifically requested or needed by HCPs within the region(s)
- Empower regional authorship and participation at local congresses & journals
- Collaboration with global team allows opportunity to capitalize on an enormous clinical/outcomes research database from timely studies
- Advanced planning provides budget for execution
- Ensure compliance with SOPs and good publication practices

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Audience Question

What is your top takeaway from regional authors & journals selection?

a. **Education** for local & regional authors on Journal specifications & evaluation and selection is needed

b. **Collaboration** between regional and global teams to take advantage of database and statistics is necessary

c. **Advanced planning** is needed to save budget

d. **All of the above**

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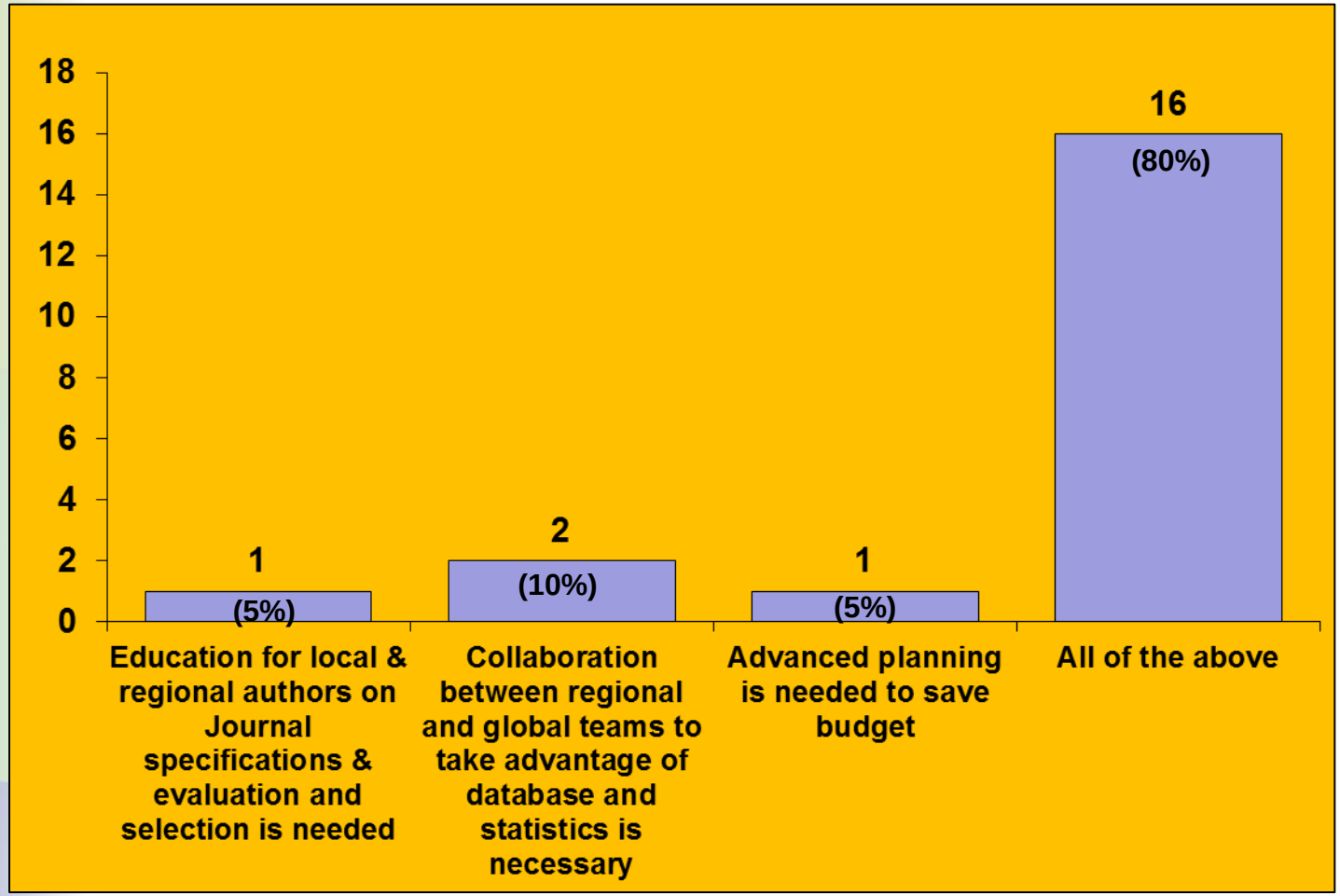
What is Your Top Takeaway from Regional Authors and Journals Selection?



Responses = 20

Publications Best Practices Include the Details

Even When It is Important Work

Michael Platt, CMPP™
President, MedVal Scientific Information Services

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Disclosure

- Michael Platt is a full-time employee of MedVal Scientific Information Services, LLC.
- He has no other conflicts of interest to disclose.
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MedVal in China

- Providing Medical Communications in China
- China and US office will support interaction with clients in China
  - Sponsored trials
  - IIS (Surveys)
  - Workshops
  - Advisory Boards
- MedVal and preferred partners have experience in Publications, Patents, and U.S. FDA Regulatory issues and contacts for SOPs and registry in China
  - Former FDA inspector, filed patents, published in *tier 1 journals*

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Audience Question

Do you work with investigators on Investigator Initiated Studies?

a. Yes

b. No

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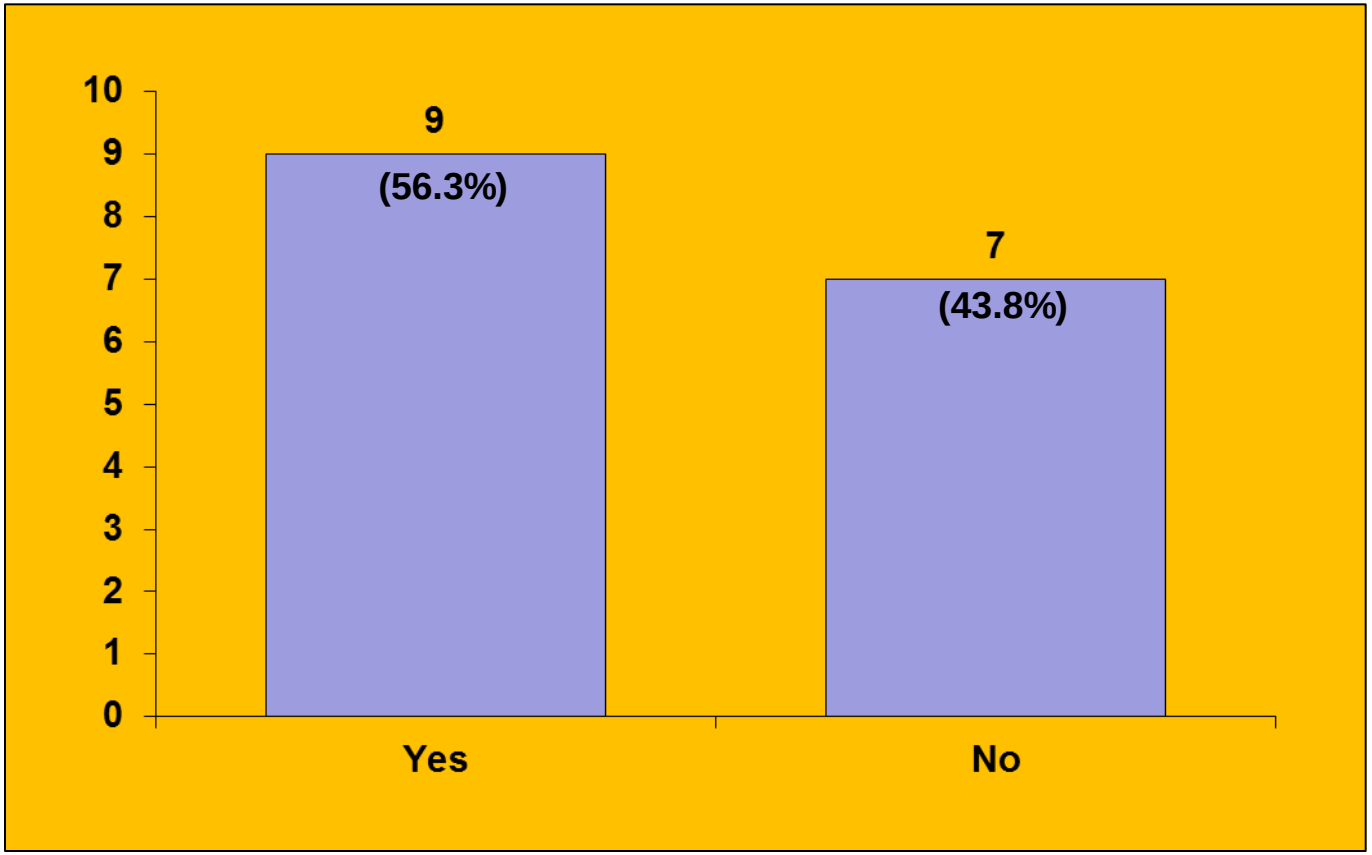
Do You Work with investigators on Investigator-Initiated Studies?



Responses = 16

Audience Question

For those projects that have challenges, what area represents the most common problems?

a. Lack of protocol

b. Study design

c. Statistics or power of study

d. Patient consent

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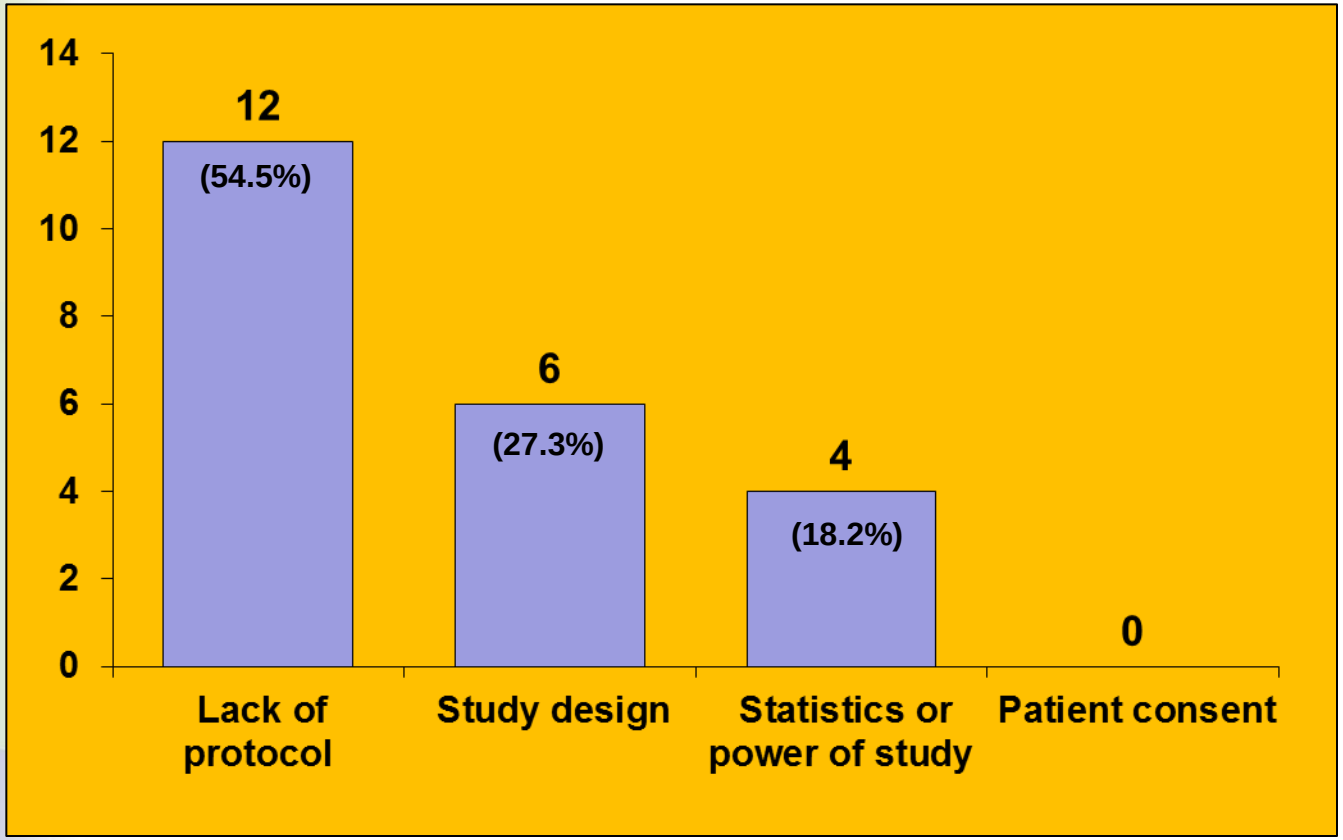
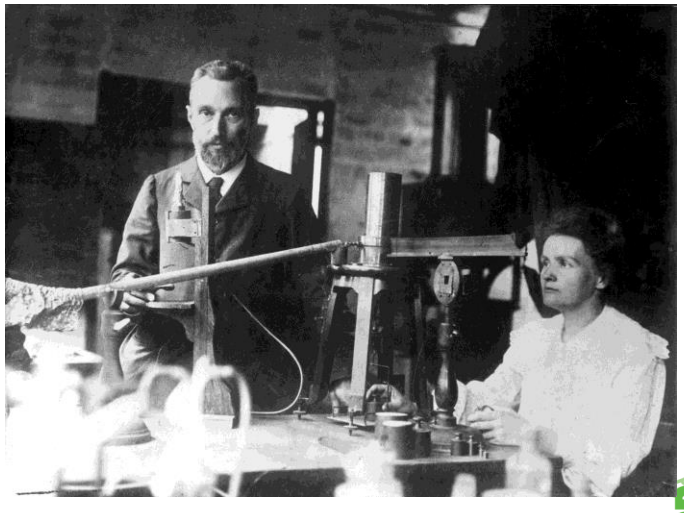
For Those Projects That Have Challenges, What Area Represents the Most Common Problems?



Responses = 22

Case: Those are Details – This is Important Work



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Case: Those are Details – This is Important Work

- Introduced to Professor/Author
- Reviewed the protocol
  - Prospective Patient Survey
    - Lacked overview of total population to be surveyed
    - Lacked statistical design/analysis
    - Lacked patient consent

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Audience Question

What is the first item you would address?

a. Lack of overview of total population to be surveyed

b. Lack of statistical design/analysis

c. Lack of patient consent

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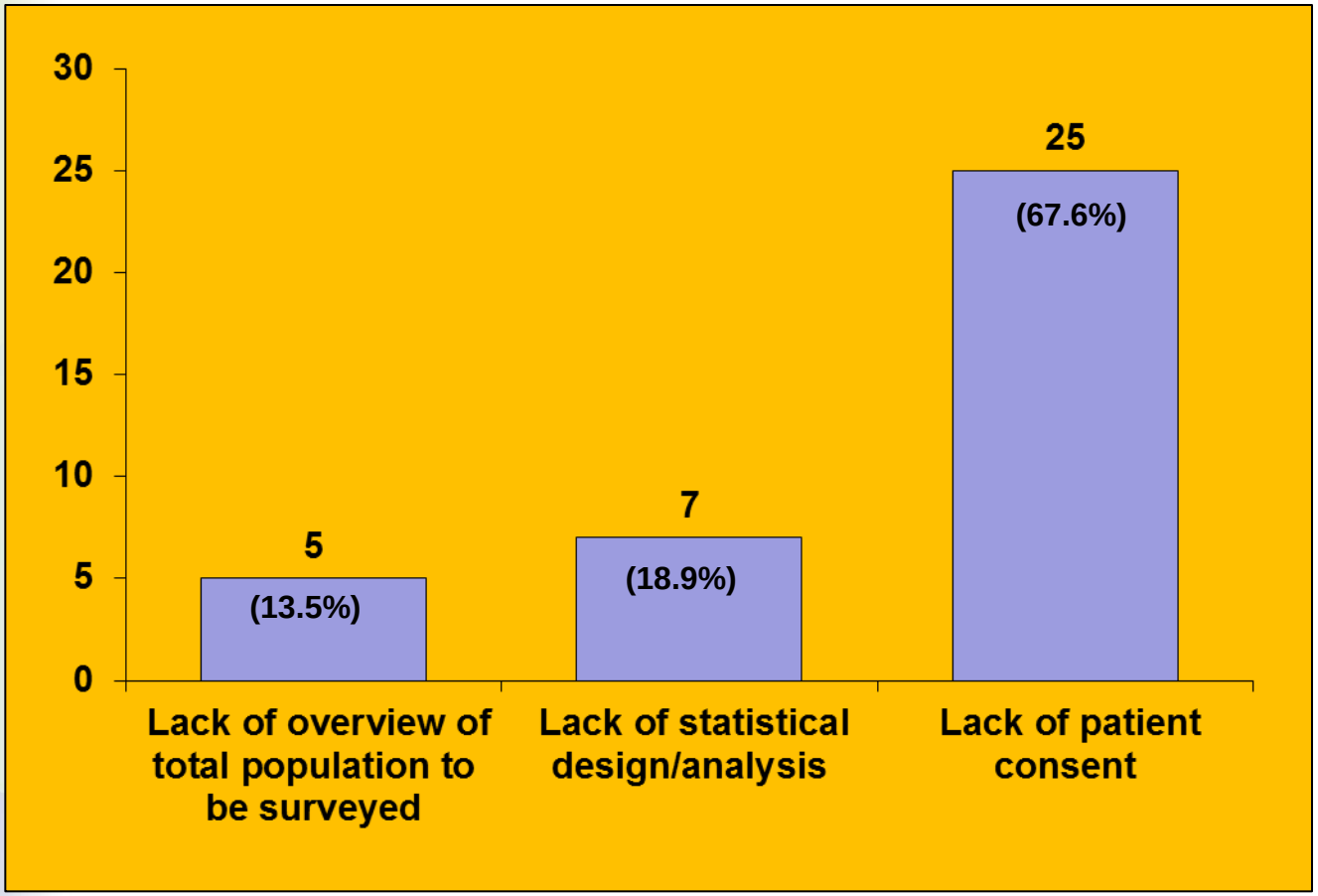
What is the First Item You Would Address?



Responses = 37

Case: Those are Details – This is Important Work

- What we did….
  - Lack of patient consent
  - Lack of overview of total population to be surveyed
  - Lack of statistical design/analysis

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What Can We Do?

- Provide Education on CONSORT and Emphasize the use of CONSORT
  - Design
  - Controls
  - Statistics Package
- “Lack of novelty and appropriate methodology is the common issue”
- “Numerous speculations within manuscripts are another common pitfall”
- “Organizing the results in a logical way to prove their hypothesis”

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Table Talk

10 minutes discussion at your table

Collect suggestions/queries for Q&A session

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Panel Q&A

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Wrap Up

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Best Practices for Regional Publications

- Educate to promote compliance with international/global company guidelines
- Ensure adequate training takes place for existing/new SOPs
  - Relate processes to day-to-day work
- Increase communication between HQ/Global and regional teams?

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Thanks to Planning Subcommittee Members

- Jill Condello
- Jodie Gillon
- Tricia Deja
- Tom Gesell
- Kirtida Pandya
- Jennifer Ciafullo
- Celeste Williams-Hughes

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Thank You!

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