2014 European Meeting of ISMPP: A New Era in Global Medical Publications
WHY DO SOME MANUSCRIPTS LAG? AN ANALYSIS OF FACTORS ASSOCIATED WITH DELIVERY TIMELINES

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DISCLOSURES

• Tom Rees, Bill Kadish, and Sheelah Smith are employees of PAREXEL International Medical Communications

Any opinions expressed are those of the authors and not necessarily those of the PAREXEL International
OBJECTIVE AND METHODS

• PAREXEL International Medical Communications is a large agency with multiple teams

• We conducted a benchmarking exercise to better understand how lead times vary across teams and what may account for this discrepancy

• Lead time was defined as the time between project initiation and manuscript submission

• Data were provided for manuscripts that were:
  • Managed by PAREXEL from initiation to submission
  • Submitted from August 2011 through August 2013
  • Primary, secondary, clinical manuscripts or reviews only
RESULTS

• We received valid data from 24 product teams across 11 client accounts

• 10 major therapy areas

• 175 manuscripts in total
  • 100 primary
  • 39 secondary
  • 36 reviews
THERE IS A WIDE VARIATION IN MANUSCRIPT LEAD TIMES

Median = 10 months
LEAD TIME VARIES SIGNIFICANTLY ACROSS PRODUCT TEAMS
PROGRAMME SIZE DOES NOT AFFECT LEAD TIME

The graph shows a scatter plot with the x-axis representing Programme output - manuscripts (n) and the y-axis representing Lead time (months). Each point represents a data point in the dataset, illustrating the relationship between programme size and lead time.
NUMBER OF AUTHORS DOES NOT AFFECT LEAD TIME

All authors

Mean ± standard deviation
MANUSCRIPT TYPE EXPLAINS SOME OF THE VARIATION IN LEAD TIME

<table>
<thead>
<tr>
<th>Lead time (months)</th>
<th>Count (n)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Primary</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
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<td>4</td>
<td>5</td>
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<td>28</td>
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<td>28</td>
<td>30</td>
</tr>
<tr>
<td>30</td>
<td>More</td>
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</table>

Median (primary) = 8.4 months
Median (secondary) = 11.0 months
Median (Review) = 11.3 months
COULD THIS EXPLAIN SOME OF THE VARIATION?
MANUSCRIPT MIX OF THE 5 LARGEST PUBLICATION ACCOUNTS

A

B

C

D

E

‘Big 5’ n= 131

Primary
Secondary
Review
Other
HOWEVER, LEAD TIMES ACROSS ACCOUNTS VARY EVEN FOR 1º MANUSCRIPTS

**All manuscript types**

<table>
<thead>
<tr>
<th>Account</th>
<th>Lead time (months)</th>
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<tbody>
<tr>
<td>A</td>
<td>9 ± 2</td>
</tr>
<tr>
<td>B</td>
<td>12 ± 3</td>
</tr>
<tr>
<td>C</td>
<td>10 ± 1</td>
</tr>
<tr>
<td>D</td>
<td>15 ± 4</td>
</tr>
<tr>
<td>E</td>
<td>8 ± 1</td>
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</tbody>
</table>

Mean ± standard error of the mean

‘Big 5’ n=131

**Primary manuscripts only**

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<th>Lead time (months)</th>
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<td>A</td>
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<td>12 ± 3</td>
</tr>
<tr>
<td>C</td>
<td>9 ± 1</td>
</tr>
<tr>
<td>D</td>
<td>16 ± 4</td>
</tr>
<tr>
<td>E</td>
<td>7 ± 1</td>
</tr>
</tbody>
</table>

‘Big 5’ n=70

P=0.05 (ANOVA)
SOME THERAPY AREAS HAVE LONGER 1º MANUSCRIPT LEAD TIMES

![Bar chart showing lead times for different therapy areas, with Fertility having the highest lead time.](chart.png)
NUMBER OF AUTHORS DOES NOT AFFECT
1º MANUSCRIPT LEAD TIME

All authors

Lead time (months)

Authors (n)

‘Big 5’ n= 70
REGARDLESS OF WHETHER YOU LOOK AT INTERNAL OR EXTERNAL AUTHORS

‘Big 5’ n= 70 (1º manuscripts only)
WHAT ABOUT THE RATIO OF INTERNAL AND EXTERNAL AUTHORS?

Account with the longest lead times

1º manuscripts only
WHAT ARE THE TEAMS’ PERSPECTIVES?

“The company put minimal resources into the brand and it was very low on their radar screens”

“There was little KOL interest in the product and therefore no pressure from that end to produce”

“The authors could not agree on the interpretation of the data”

“Additional analyses were needed, which took some time to develop”

“Happy manuscripts are all alike; every unhappy manuscript is unhappy in its own way”

Tolstoy
CONCLUSIONS

• Although manuscript type significantly affects lead times, other factors also contribute.
• Overall number of authors does not affect lead times; the balance of internal and external authors may do so.
• Client account and therapy area specific practices may contribute.
• The next step is further qualitative analyses to identify optimal working practices.
A SURVEY OF CURRENT PRACTICES IN ENCORE ABSTRACT SUBMISSIONS FROM INDUSTRY-SPONSORED STUDY DATA

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Information presented reflects the personal knowledge and opinion of the authors and does not represent the position of their current or past employees or the position of ISMPP.
Definition of encore abstract: resubmission of an original abstract with minor changes in line with congress guidelines

**Rationale for Survey**

- Definition of encore abstract: resubmission of an original abstract with minor changes in line with congress guidelines

  - **Encore abstracts**
    - **Rationale?**
      - Different audience, country, language, etc.
    - **Guidelines?**
      - ICMJE, GPP2, Congress?
        - Changes in authorship from original acceptable?
        - Who should present if original authors are not available or local language presenters are needed?
    - **Copyright?**
      - Do you consider copyright from the original?
• A 20-question online survey

• The survey was piloted by a small group of experienced publication professionals

• It was forwarded to ISMPP members via email and posted on the Publication Plan website

• The survey was open from 19th July to 31st August, 2013
Where is your current place of work?

- Industry: 50%, n=98
- Agency: 46%, n=89
- Freelancer: 3%, n=6
- Other: 1%, n=2

If you selected industry, please select the size of your company?

- <1000 employees: 21%, n=22
- 1000-9000 employees: 27%, n=28
- >9000 employees: 52%, n=54

Answered/Skipped = 195/0

Industry: pharma, biotech, medical device companies

Answered/Skipped = 104/91
What is the location of your current place of work?

- USA: 66% (n=120)
- UK: 19% (n=34)
- Europe: 9% (n=19)
- Asia: 4% (n=8)

What is the reach of your current role?

- Local: 6% (n=11)
- Regional: 15% (n=29)
- Global: 79% (n=152)

Europe: Belgium, Denmark, France, Germany, Netherlands, Spain, Switzerland
Asia: Australia, India, Japan, Singapore

Answered/Skipped = 182/13
Answered/Skipped = 192/3
CURRENT ROLE

How long have you been in this role?

- 0 to 3 years: 39%, n=76
- 4 to 6 years: 26%, n=51
- 7 to 14 years: 25%, n=48
- >15 years: 9%, n=8

Answered/Skipped = 193/2

What is your current role?

- Editorial: 61%, n=118
- Senior management: 26%, n=51
- Accounts: 9%, n=17
- Other: 4%, n=8

Answered/Skipped = 188/7

Medical writing experience = 69% (mean ± SD, 11.7 ± 7 years)
# ICMJE Criteria for Abstract Submissions

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes (%)</th>
<th>No (%)</th>
<th>Partially/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Does your company follow the ICMJE uniform requirements for manuscripts for abstract submissions?</td>
<td>91% (175)</td>
<td>5% (9)</td>
<td>4% (5) partially/follow congress guidelines/follow spirit of guidelines</td>
</tr>
<tr>
<td>**Do you believe the ICMJE uniform requirements for manuscripts applies for abstract submissions?</td>
<td>84% (162)</td>
<td>10% (19)</td>
<td>7% (13) partially/more flexibility/follow congress guidelines/follow spirit of guidelines</td>
</tr>
</tbody>
</table>

*Answered/Skipped = 184/1 1
**Answered/Skipped = 181/1 4
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does your current workplace provide any specific guidance on presenting encore data?</td>
<td>35% (67)</td>
<td>28% (53)</td>
<td>37% (70) follow client SOPs, policies and guidance</td>
</tr>
</tbody>
</table>
GUIDANCE ON PRESENTING ENCORE DATA (II)

If yes, does the guidance cover the following? (not mutually exclusive)

- Appropriateness of submitting encore data: 76%
- Adding authors as per GPP2: 51%
- Requirements for new authorship: 48%
- Changes to sequence of authors: 38%
- Number of congresses: 23%
- Number of different audiences: 21%

*Answered/Skipped = 85/110
What is the maximum times an abstract should be presented at various congresses?

- **No limit**: n=9 (5%)
- **In moderation (different country/audience)**: n=129 (71%)
- **Limited (up to 5 different countries/congresses)**: n=17 (9%)
- **Very limited (1 different country/audience)**: n=14 (8%)
- **None**: n=3 (2%)
- **Up to the authors to decide**: n=10 (5%)

*Answered/Skipped = 182/13*
What are your opinions on authorship of encore abstracts? (not mutually exclusive)

- Original authors can be removed if they prefer: 73% (n=132)
- Additional author(s) should NOT be included: 53% (n=96)
- An additional author can be included as a presenter with relevant language skills: 49% (n=89)
- An additional author could be included if all authors are in agreement: 30% (n=55)
- Additional author (s) can be included if wording changes are made: 12% (n=22)

*Answered/Skipped = 182/13
### PRESENTATION OF ENCORE ABSTRACTS

**Who is appropriate to present encore data? (not mutually exclusive)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
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<tbody>
<tr>
<td>Is only an author appropriate to present?</td>
<td>Yes: 46% (84)</td>
</tr>
<tr>
<td>Is a non-author appropriate to present if the authors are not available and congress guidelines permit?</td>
<td>Yes: 55% (100)</td>
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</table>

Answered/Skipped = 182/13
What reasons, if any, validate encore data submissions? (not mutually exclusive)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Response</th>
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<tbody>
<tr>
<td>Different geography</td>
<td>95% (172)</td>
</tr>
<tr>
<td>Different specialty</td>
<td>94% (171)</td>
</tr>
<tr>
<td>None/other</td>
<td>3% (5)</td>
</tr>
</tbody>
</table>

Other: where original submission is unavailable, adding practical application of data for different audience

Answered/Skipped = 182/13
### CONSISTENCY OF ENCORE SUBMISSIONS

<table>
<thead>
<tr>
<th>Question</th>
<th>Majority response</th>
</tr>
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<tbody>
<tr>
<td>Do the same authorship rules apply for a global/international congress that accepts encores vs a local congress?</td>
<td>93% (170) Yes</td>
</tr>
</tbody>
</table>

Answered/Skipped = 182/13
GUIDANCE AND COPYRIGHT WITH RESPECT TO ENCORE SUBMISSIONS

Should there be more guidance from the publication/medical writing organizations on encore abstracts?
- Yes: 78%, n=141
- No: 22%, n=39

Answered/Skipped = 180/15

Do you consider the original copyright when submitting an encore abstract?
- Yes: 57%, n=93
- No: 43%, n=69

Answered/Skipped = 162/33
LIMITATIONS/COMMENTS OF INTEREST

• **Limitations:** there may have been a selection bias as those who participated had an interest in encore abstract submissions

• **Comments of interest:**
  
  • Congress secretariats could provide additional input

  • Copyright, ie, what is considered a significant change to an encore abstract to avoid obtaining copyright permissions?

  • Timelines for encores: is it appropriate to submit an encore once a manuscript is accepted for publication?
SUMMARY

- In general, encores were considered appropriate for different countries/audiences

- Respondents overwhelmingly indicated that they followed the ICMJE authorship criteria for development of congress abstracts although authorship practices varied widely for encore abstract submissions

- Most of the respondents would like to see more detailed guidance from ISMPP:
  - Appropriateness of submitting/presenting encore data
  - Process for authorship selection

- Copyright of the original abstract was considered by only 57% of respondents
CONCLUSIONS

• We recommend that companies form a clear position governing the appropriateness of encore abstract submissions

• We would like to see further recommendations from ISMPP on encore abstract submissions
ACKNOWLEDGEMENTS

Thank you to everyone who completed the questionnaire