



**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

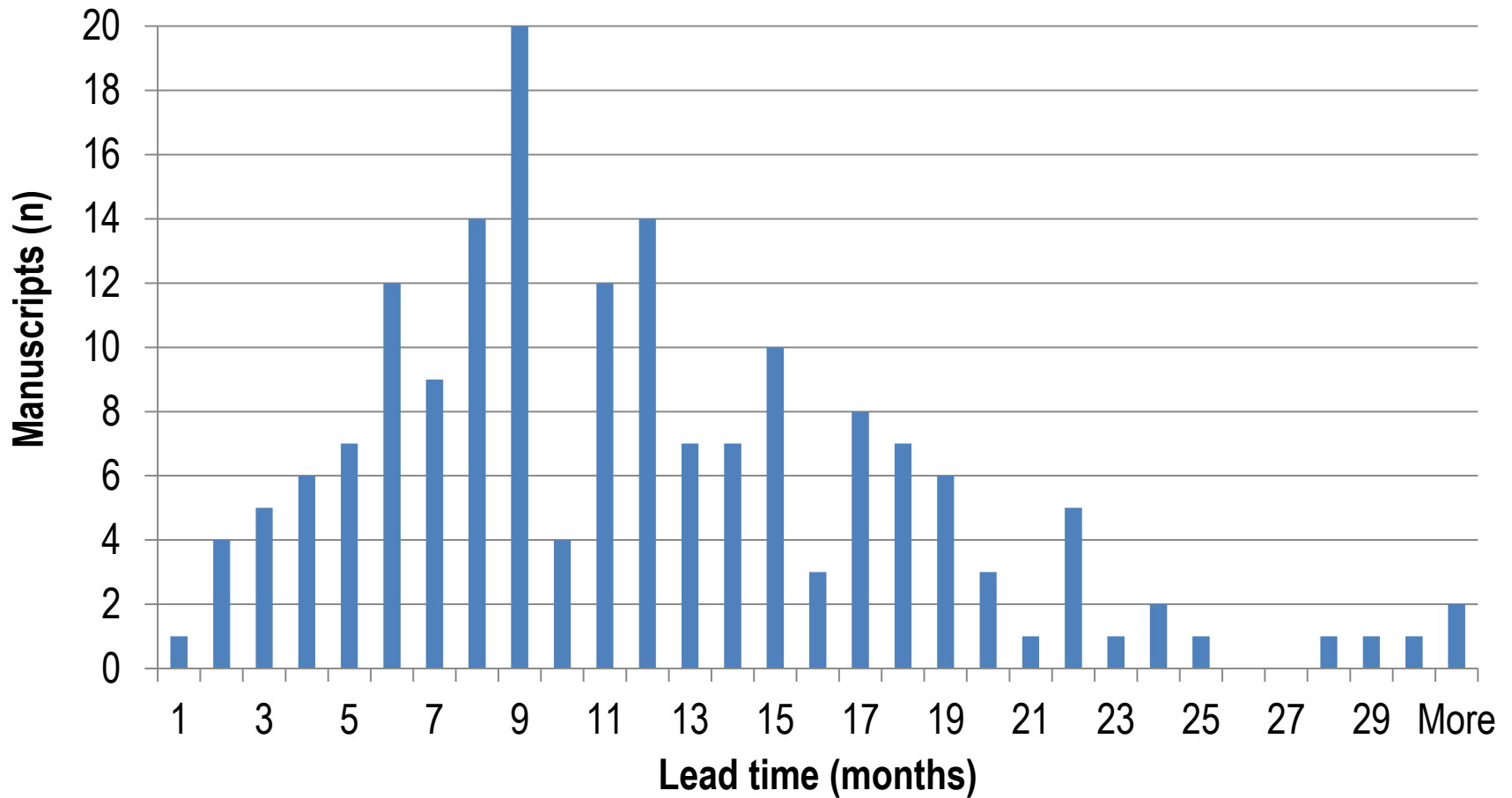
# OBJECTIVE AND METHODS

- 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

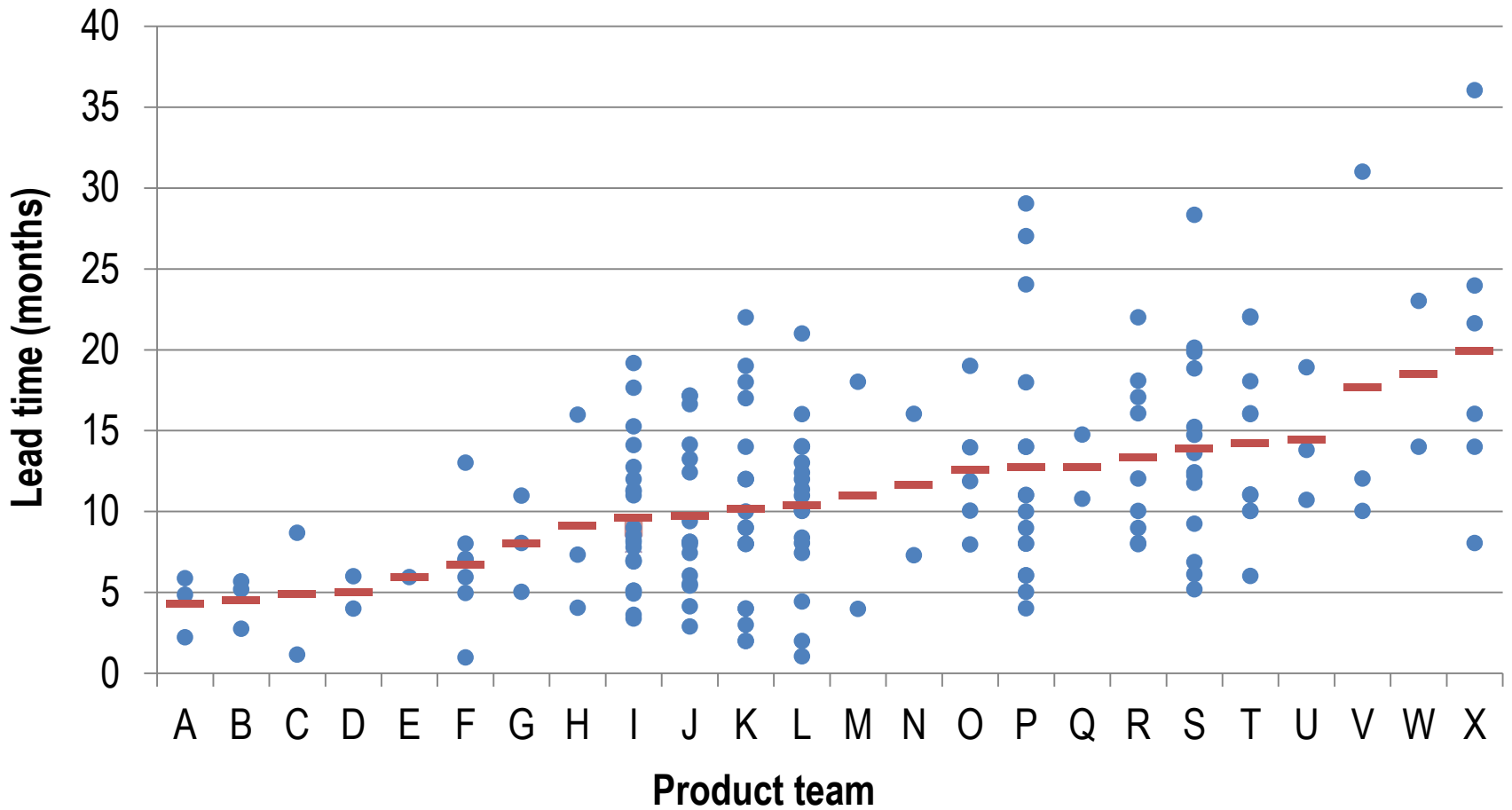
- We received valid data from 24 product teams across 11 client accounts
- 10 major therapy areas
- 175 manuscripts in total
  - 100 primary
  - 39 secondary
  - 36 reviews

# THERE IS A WIDE VARIATION IN MANUSCRIPT LEAD TIMES

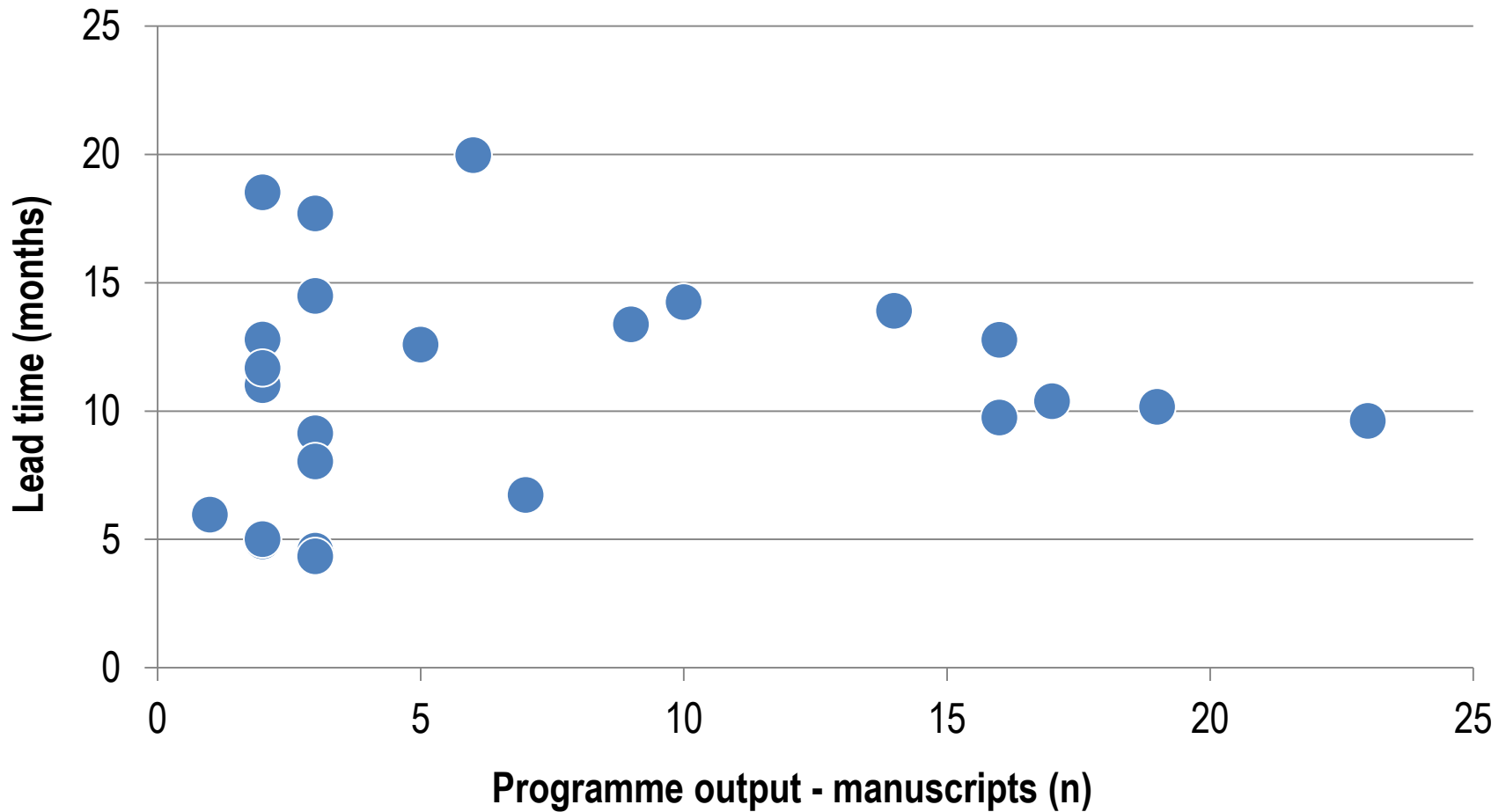


Median = 10 months

# LEAD TIME VARIES SIGNIFICANTLY ACROSS PRODUCT TEAMS



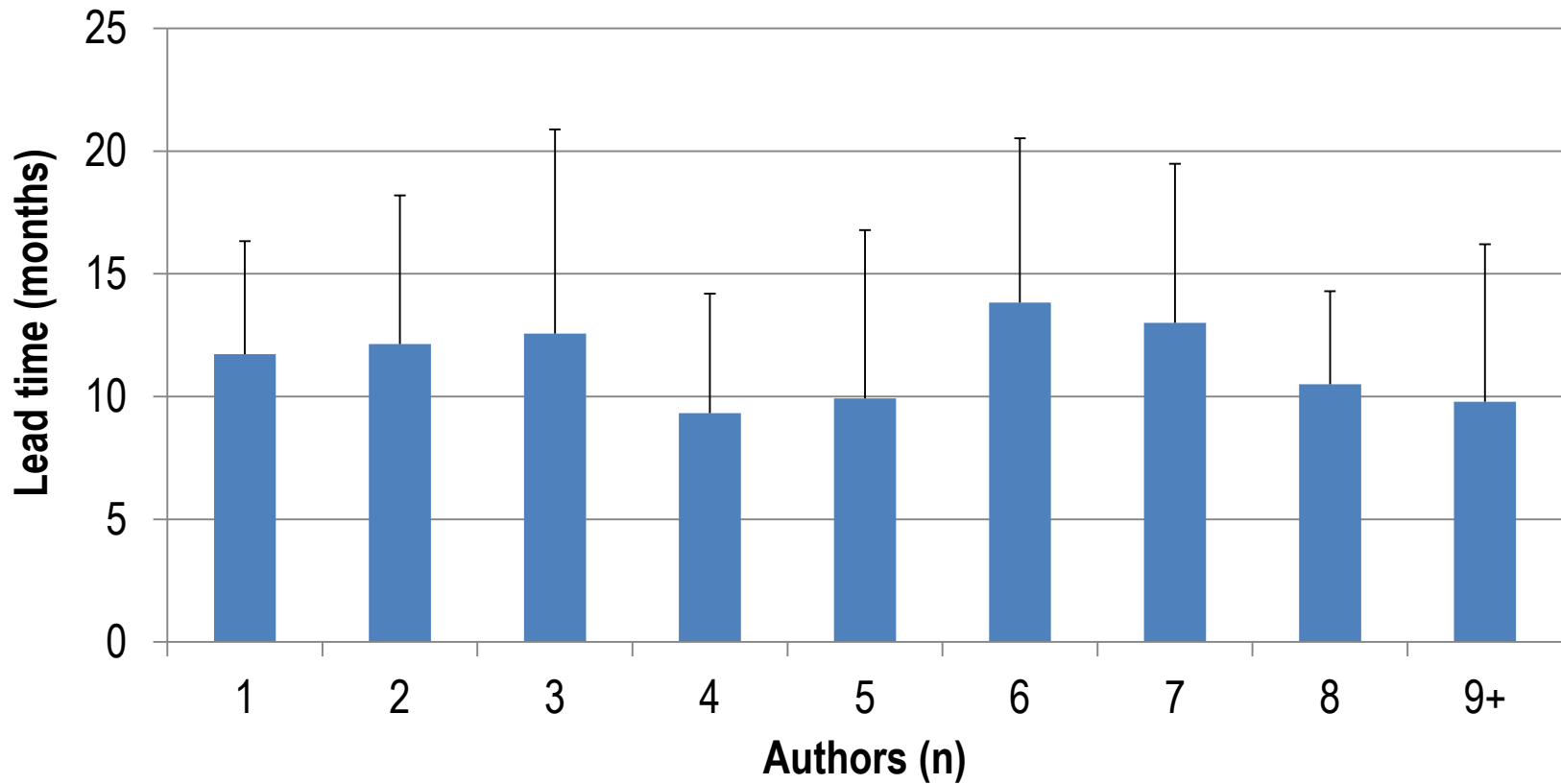
# PROGRAMME SIZE DOES NOT AFFECT LEAD TIME





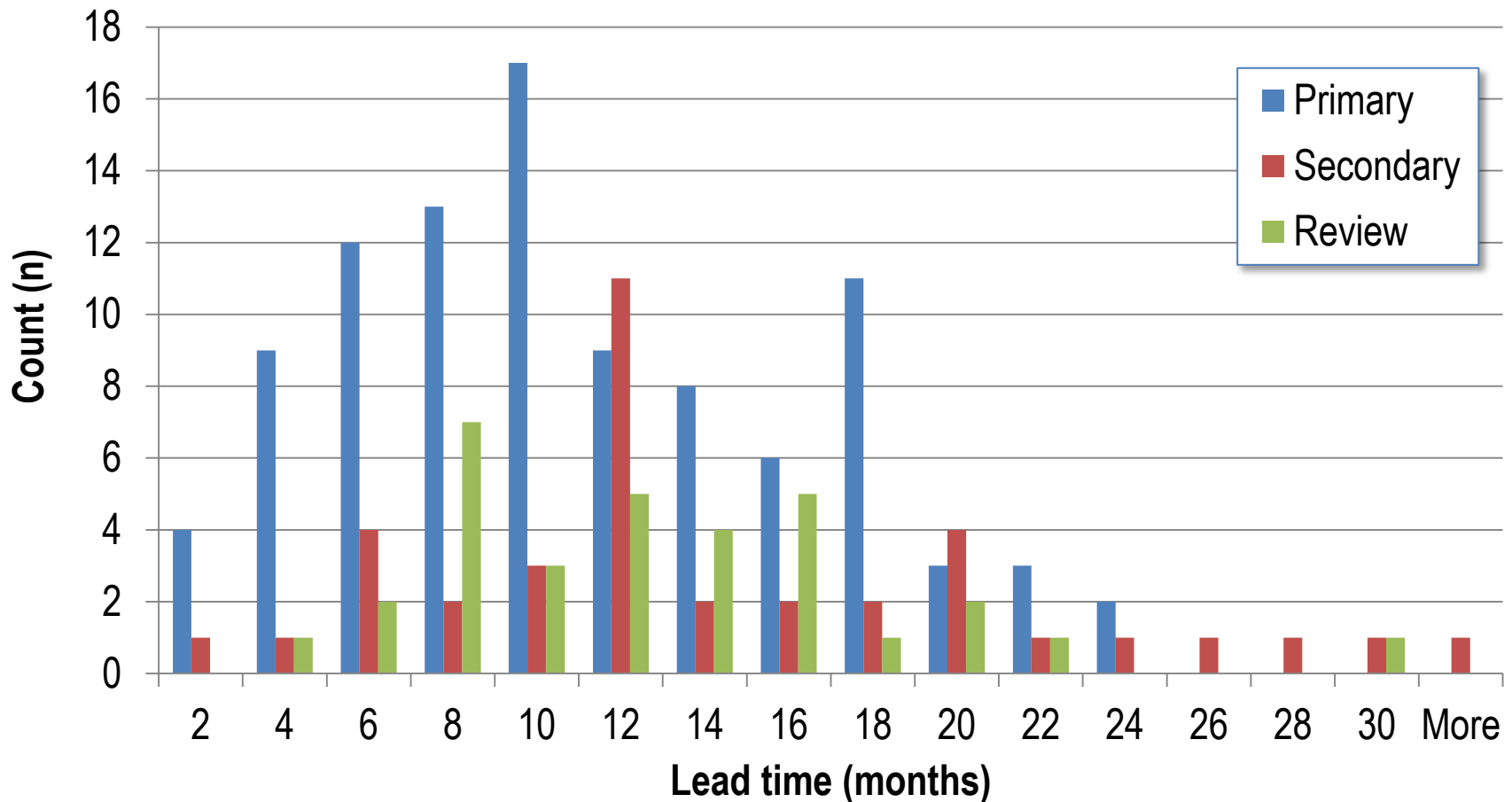
# NUMBER OF AUTHORS DOES NOT AFFECT LEAD TIME

## All authors



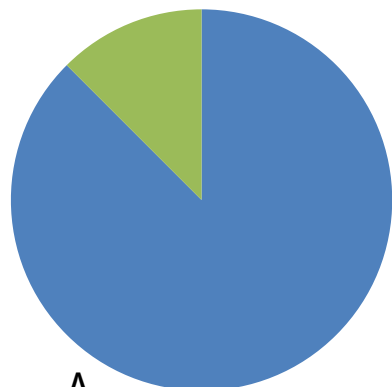
Mean  $\pm$  standard deviation

# MANUSCRIPT TYPE EXPLAINS SOME OF THE VARIATION IN LEAD TIME

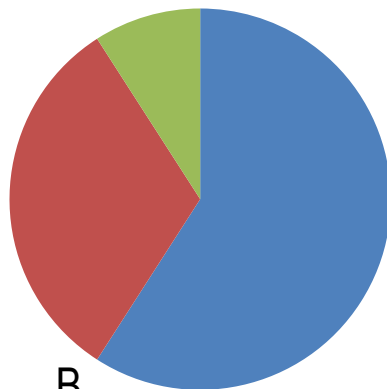


Median (primary) = 8.4 months  
Median (secondary) = 11.0 months  
Median (Review) = 11.3 months

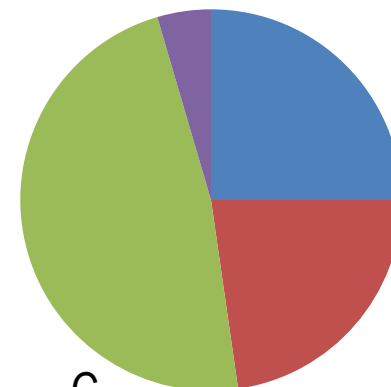
# COULD THIS EXPLAIN SOME OF THE VARIATION? MANUSCRIPT MIX OF THE 5 LARGEST PUBLICATION ACCOUNTS



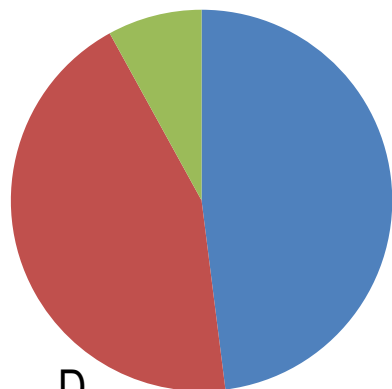
A



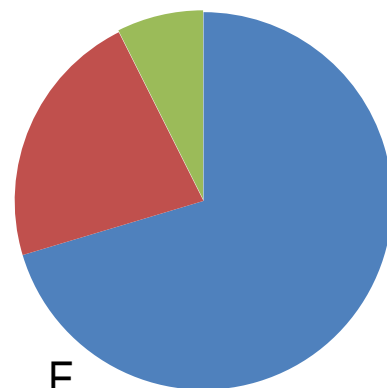
B



C



D



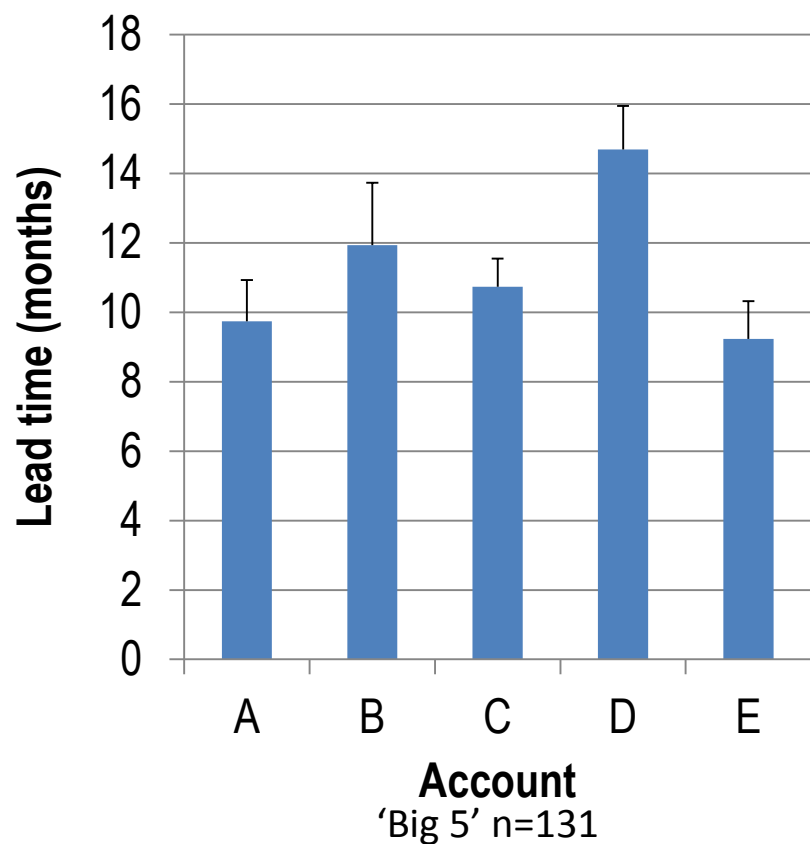
E



'Big 5' n= 131

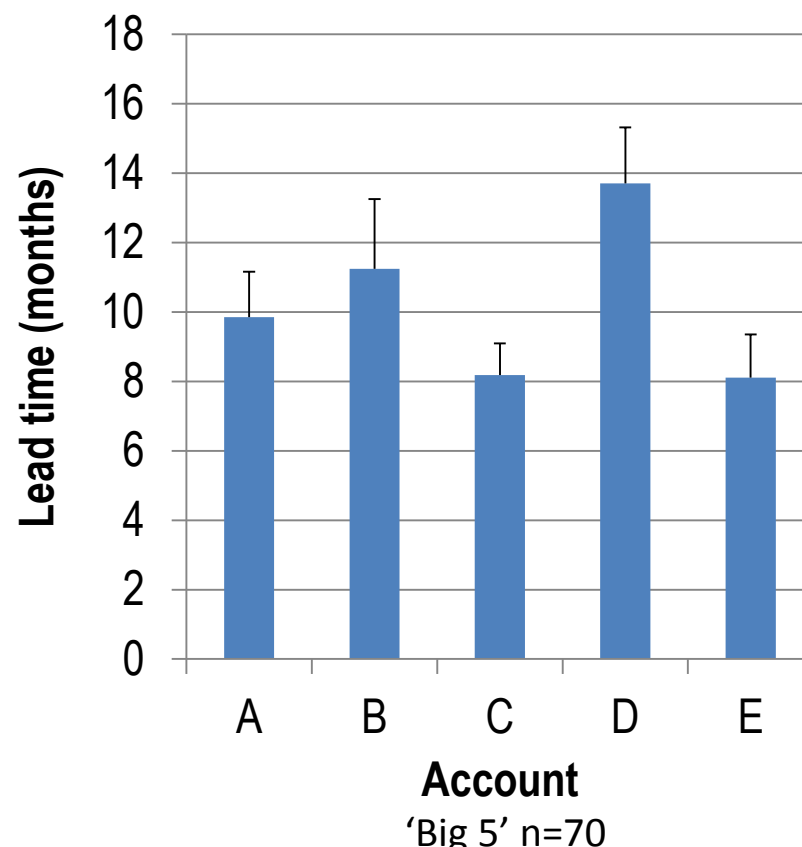
# HOWEVER, LEAD TIMES ACROSS ACCOUNTS VARY EVEN FOR 1° MANUSCRIPTS

## All manuscript types



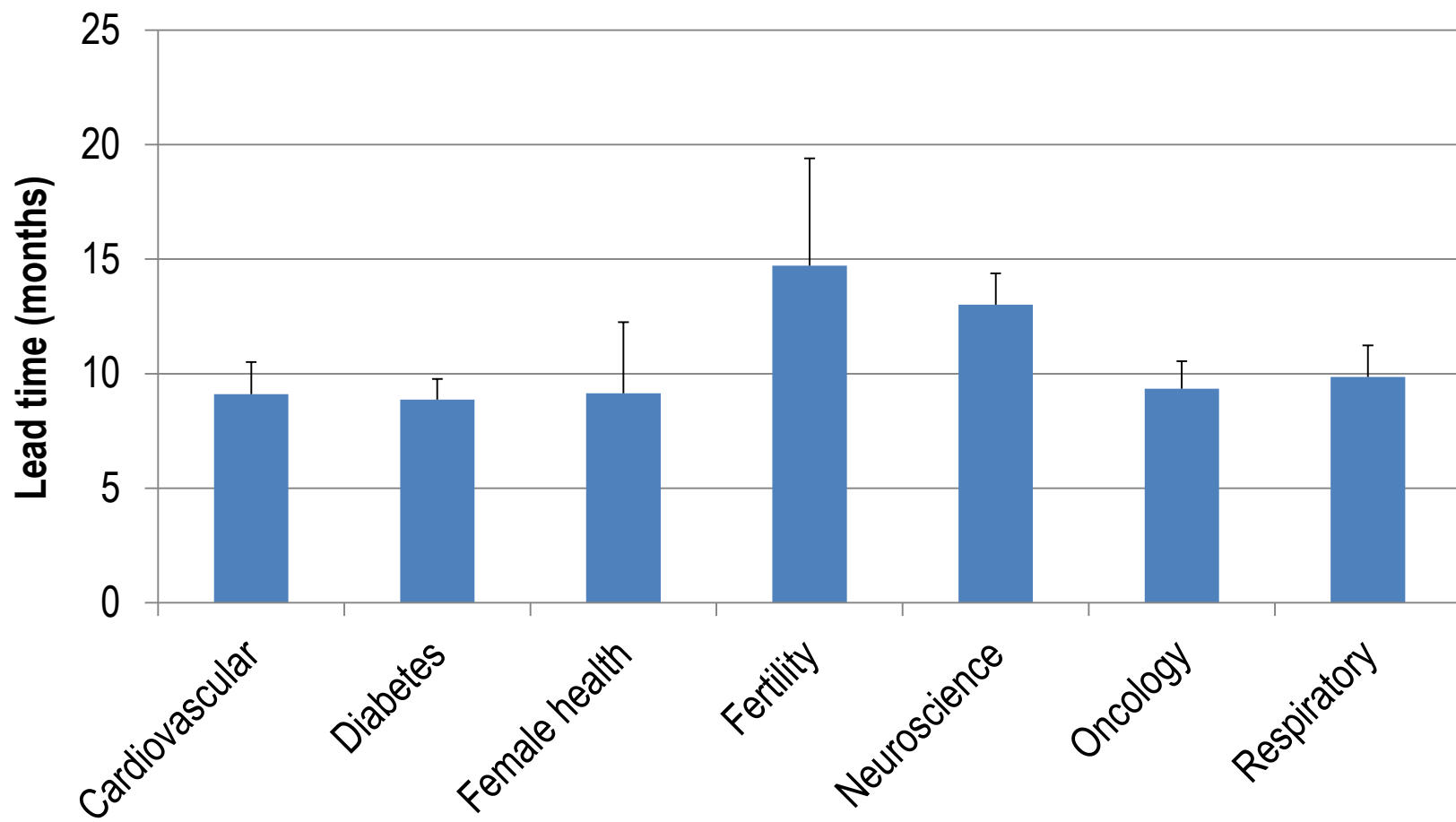
Mean  $\pm$  standard error of the mean

## Primary manuscripts only



$P=0.05$  (ANOVA)

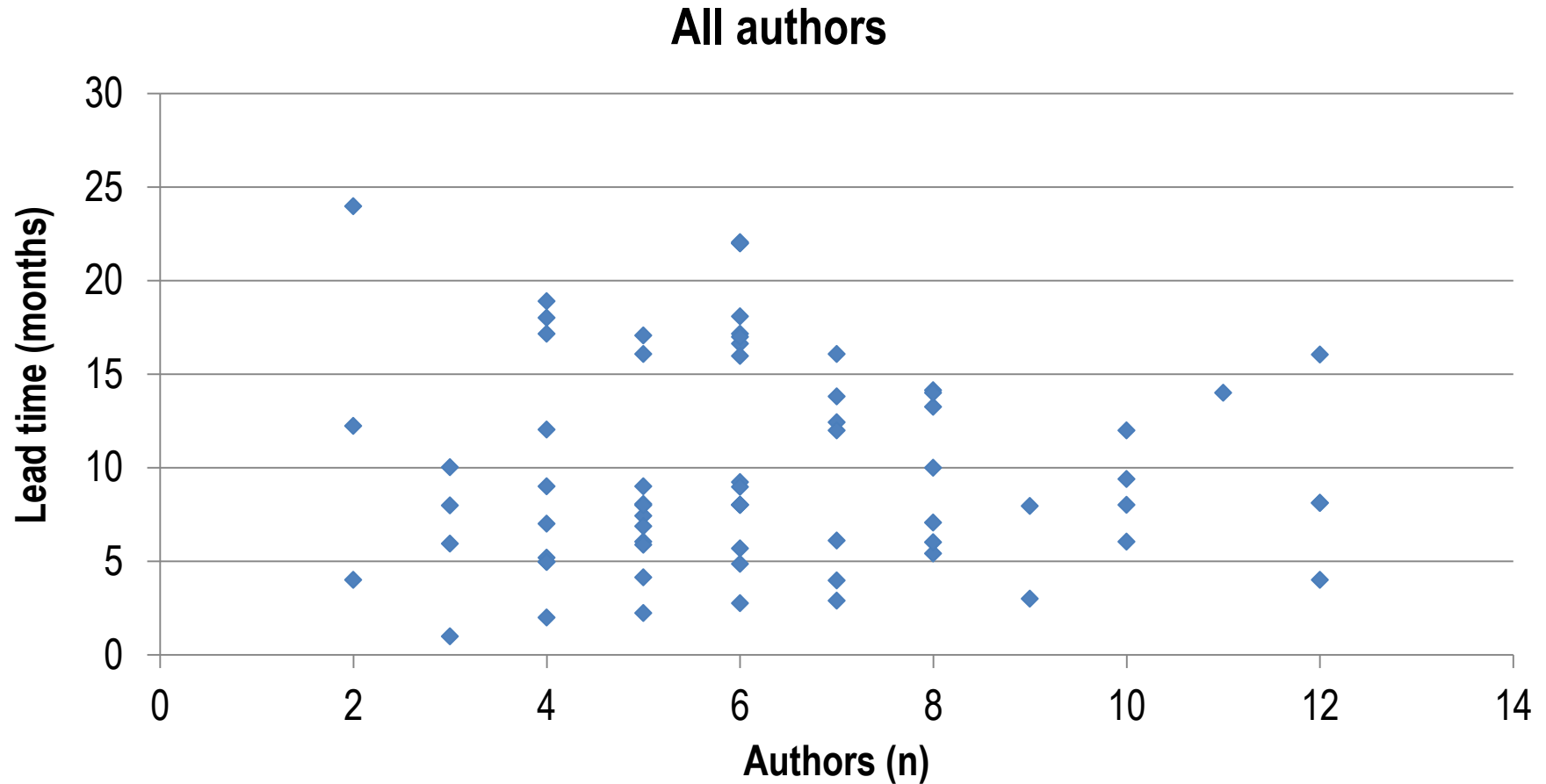
# SOME THERAPY AREAS HAVE LONGER 1<sup>o</sup> MANUSCRIPT LEAD TIMES



Mean  $\pm$  sem

All (n=175)

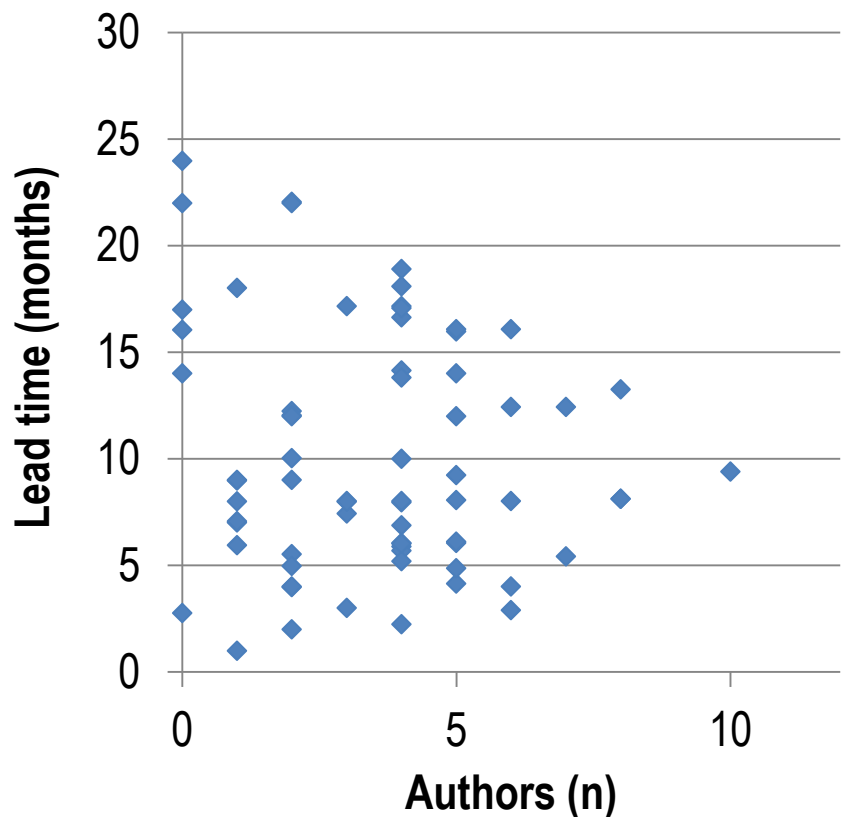
# NUMBER OF AUTHORS DOES NOT AFFECT 1<sup>o</sup> MANUSCRIPT LEAD TIME



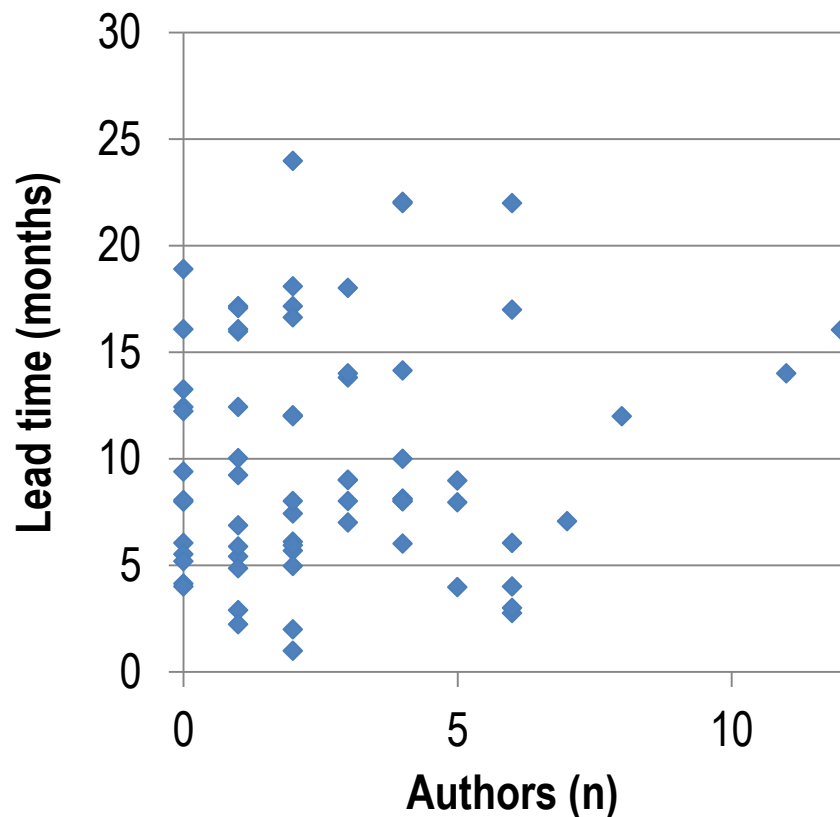
'Big 5' n= 70

# REGARDLESS OF WHETHER YOU LOOK AT INTERNAL OR EXTERNAL AUTHORS

## Internal authors

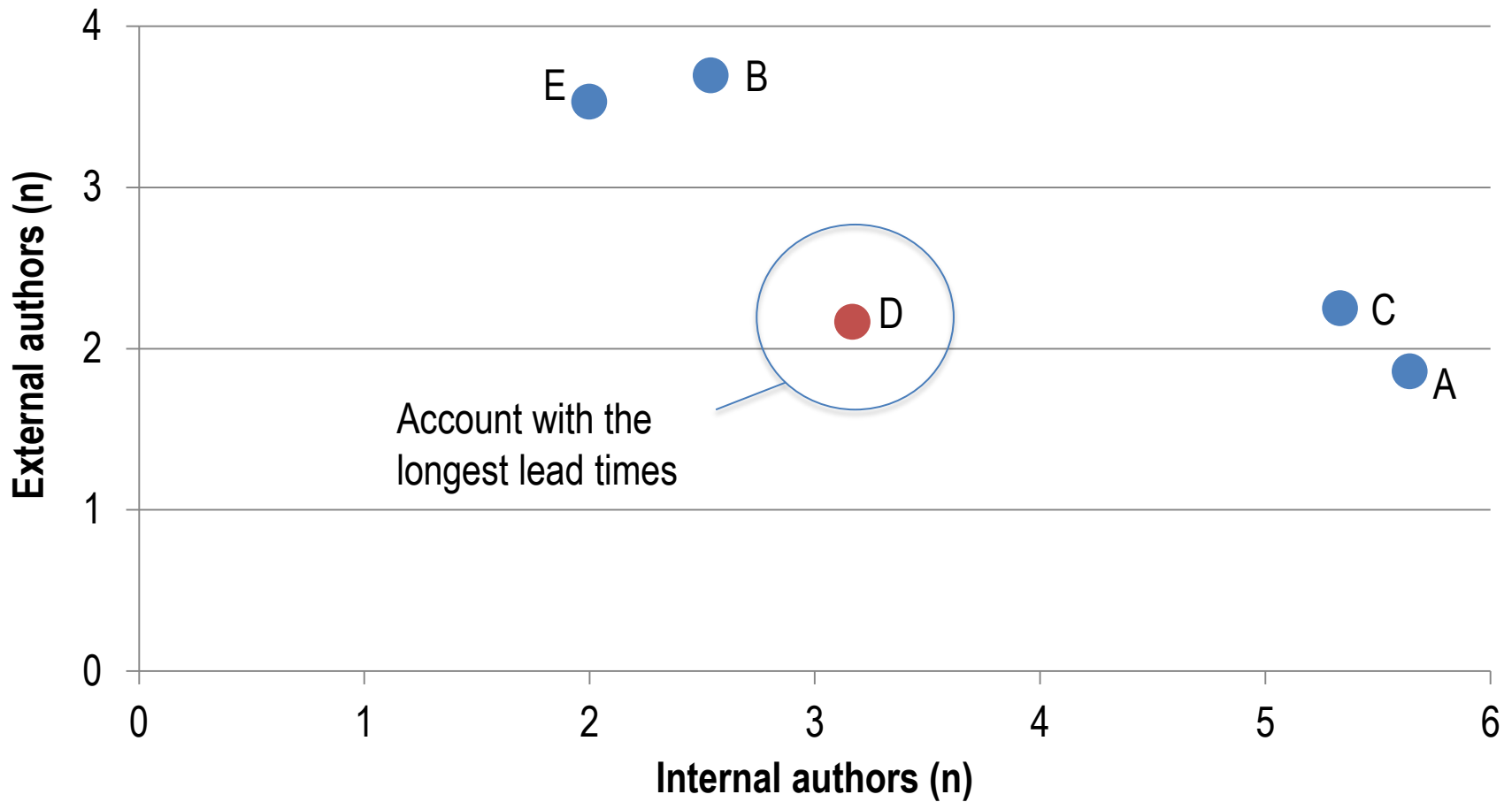


## External authors



'Big 5' n= 70 (1<sup>o</sup> manuscripts only)

# WHAT ABOUT THE RATIO OF INTERNAL AND EXTERNAL AUTHORS?





# WHAT ARE THE TEAMS' PERSPECTIVES?

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

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

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

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

**“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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<sup>a</sup>Shire, Eysins, Switzerland; <sup>b</sup>Shire, Diegem, Belgium; <sup>c</sup>Caudex Medical, Oxford, UK

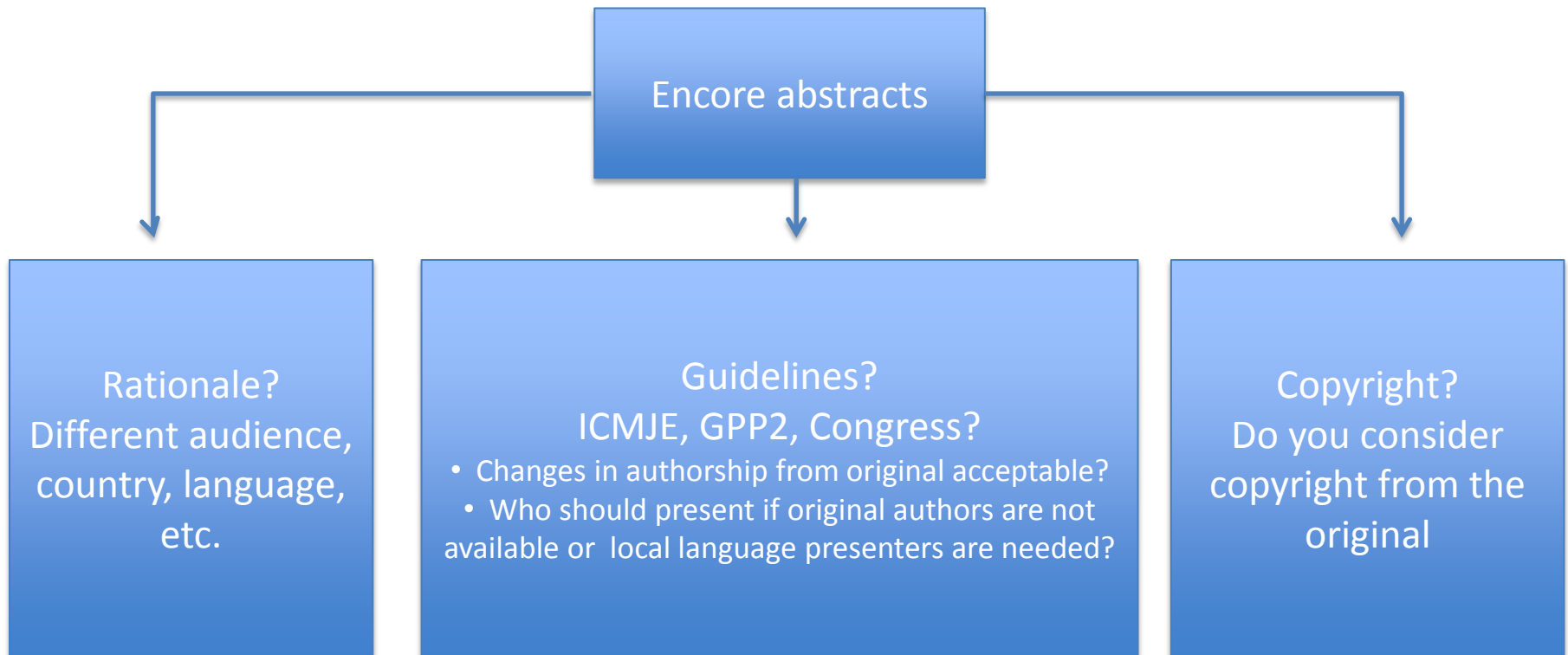


# DISCLOSURES

- 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

# RATIONALE FOR SURVEY

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

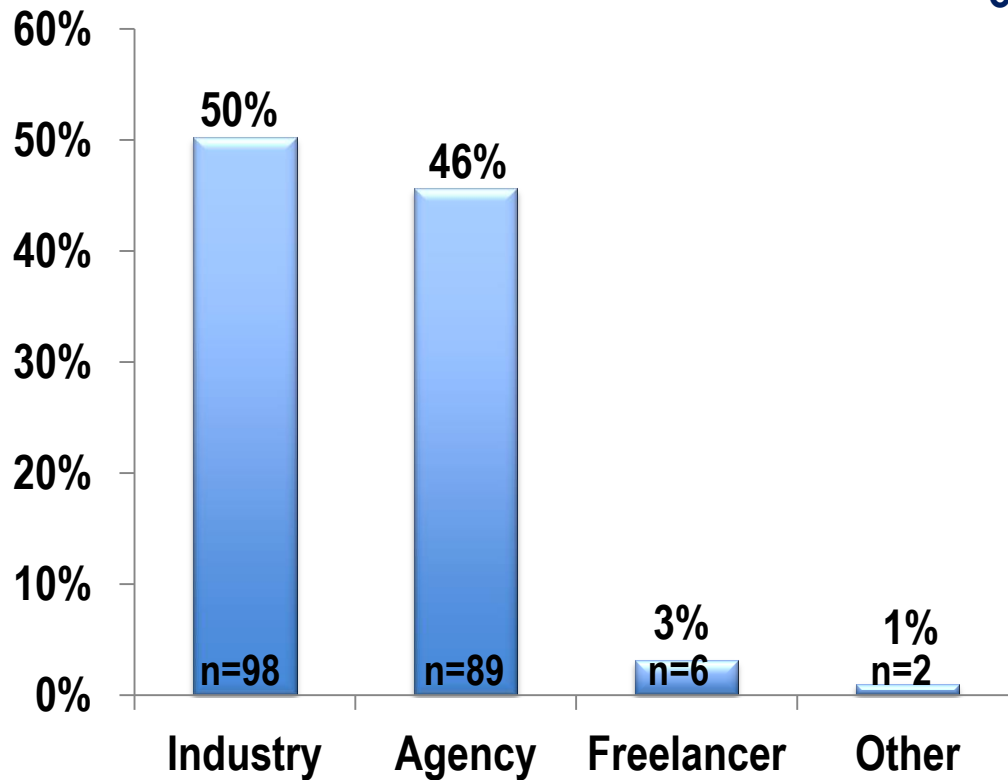


# FRAMEWORK

- 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 19<sup>th</sup> July to 31<sup>st</sup> August, 2013

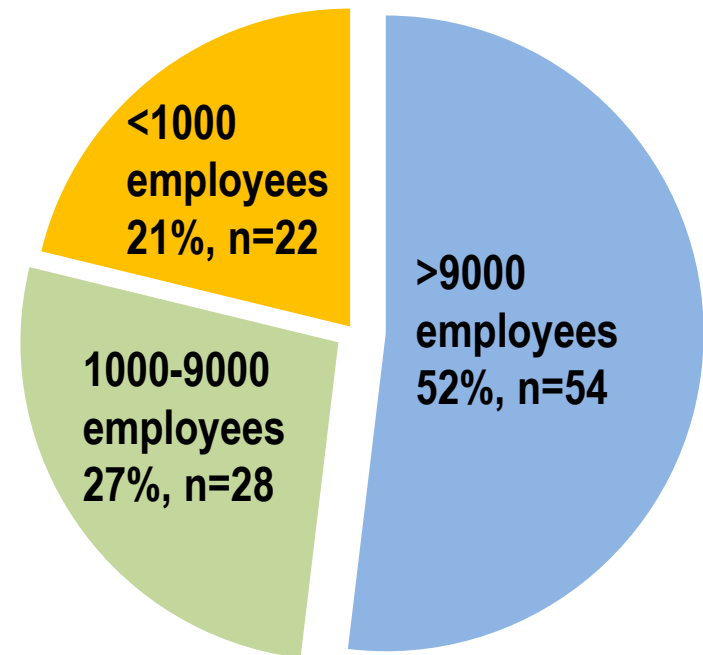
# DEMOGRAPHICS

Where is your current place of work?



Answered/Skipped = 195/0

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

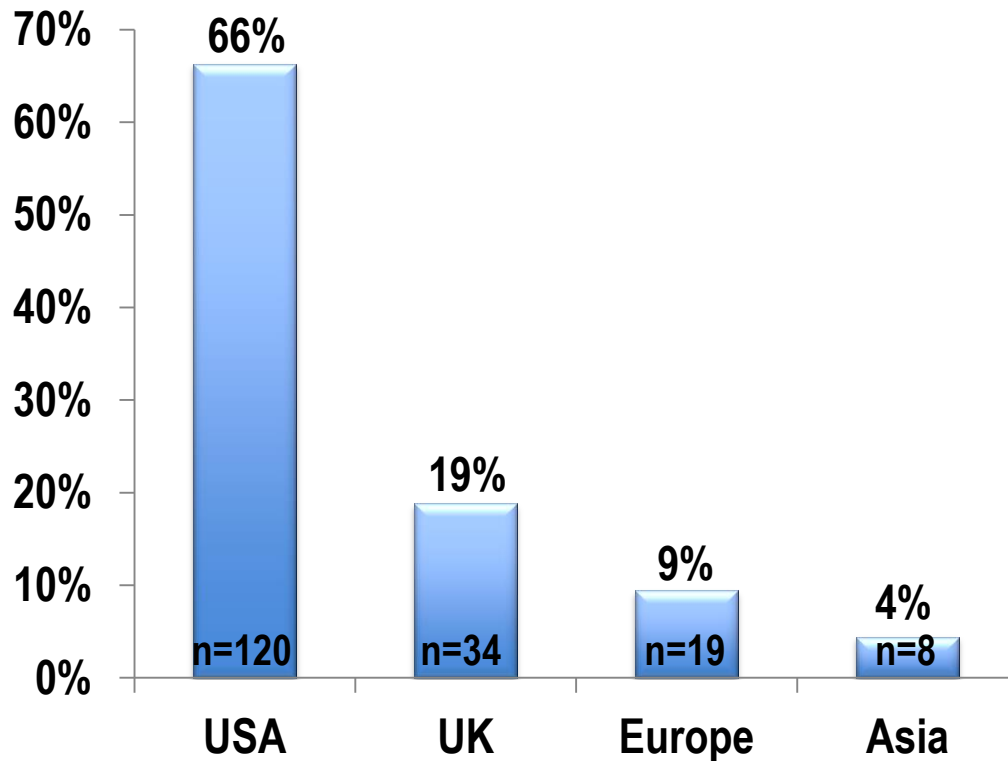


Answered/Skipped = 104/91

Industry: pharma, biotech, medical device companies

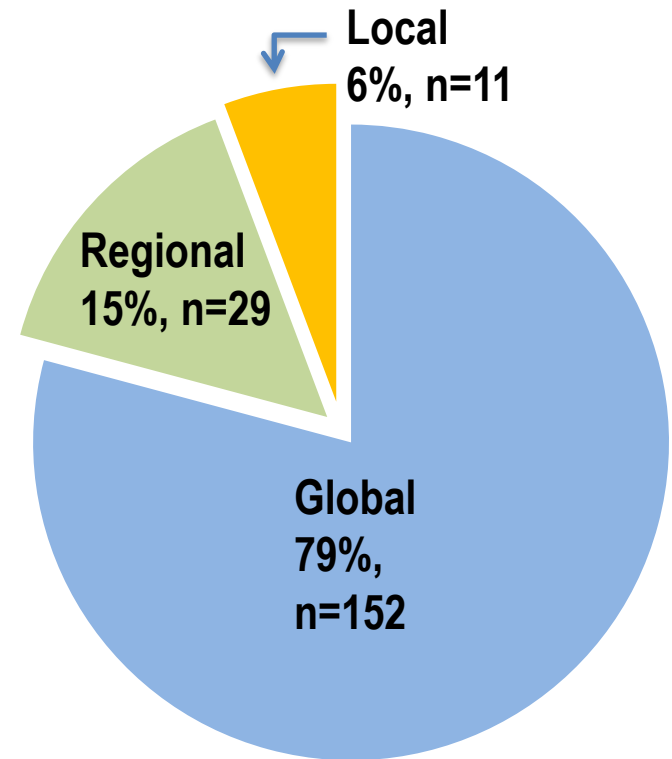
# GEOGRAPHY

What is the location of your current place of work?



Answered/Skipped = 182/13

What is the reach of your current role?



Answered/Skipped = 192/3

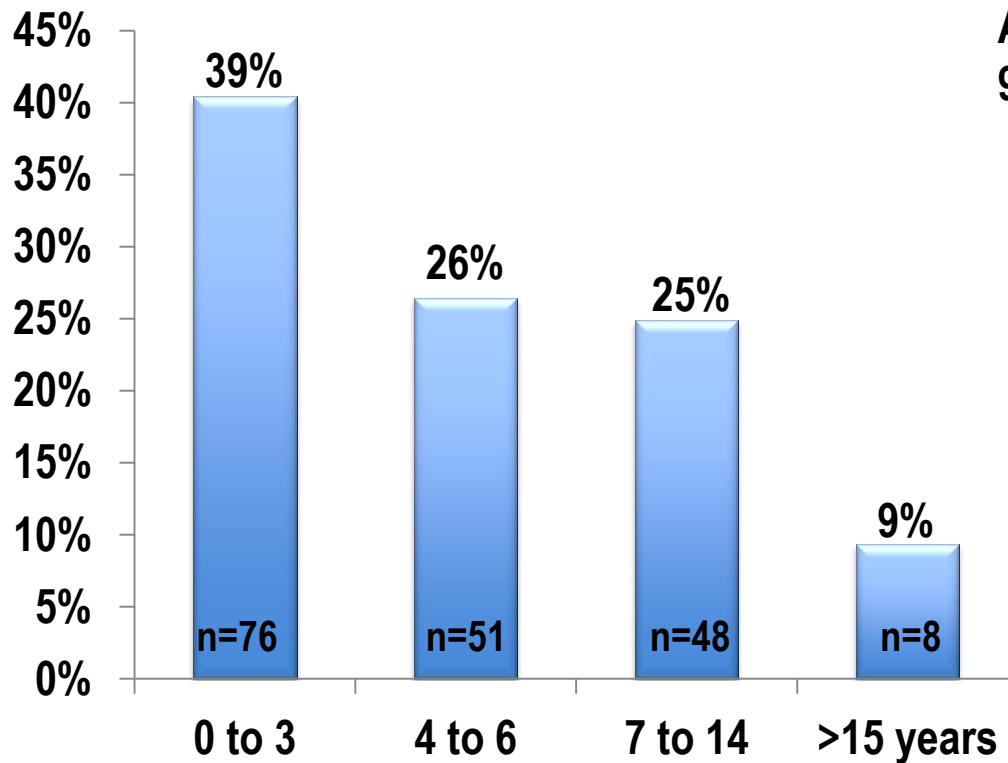
Europe: Belgium, Denmark, France, Germany, Netherlands, Spain, Switzerland

Asia: Australia, India, Japan, Singapore



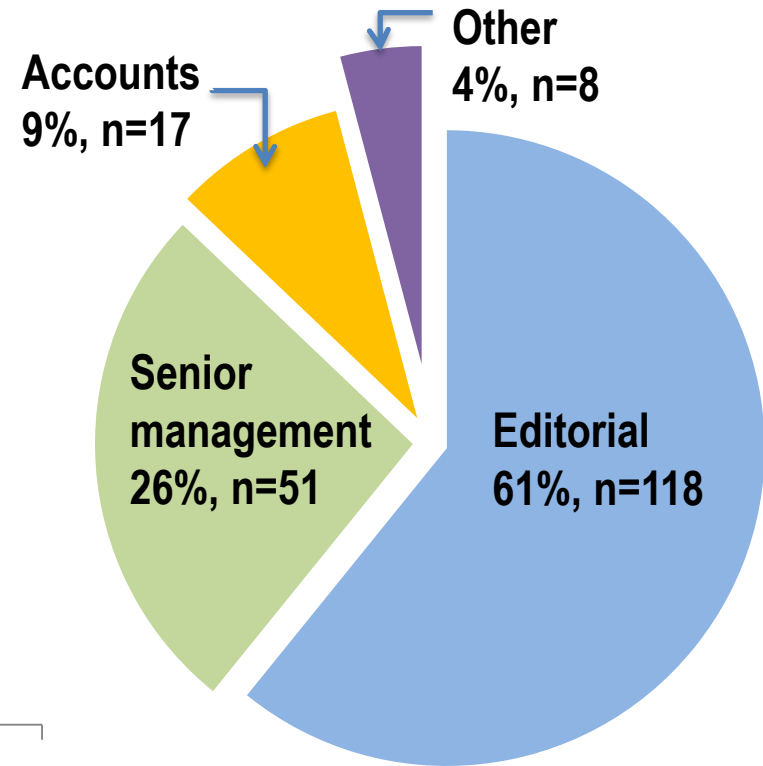
# CURRENT ROLE

## How long have you been in this role?



Answered/Skipped = 193/2

## What is your current role?



Answered/Skipped = 188/7

Medical writing experience = 69% (mean  $\pm$  SD, 11.7  $\pm$  7 years)

# ICMJE CRITERIA FOR ABSTRACT SUBMISSIONS

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

\*Answered/Skipped = 184/11

\*\*Answered/Skipped = 181/14

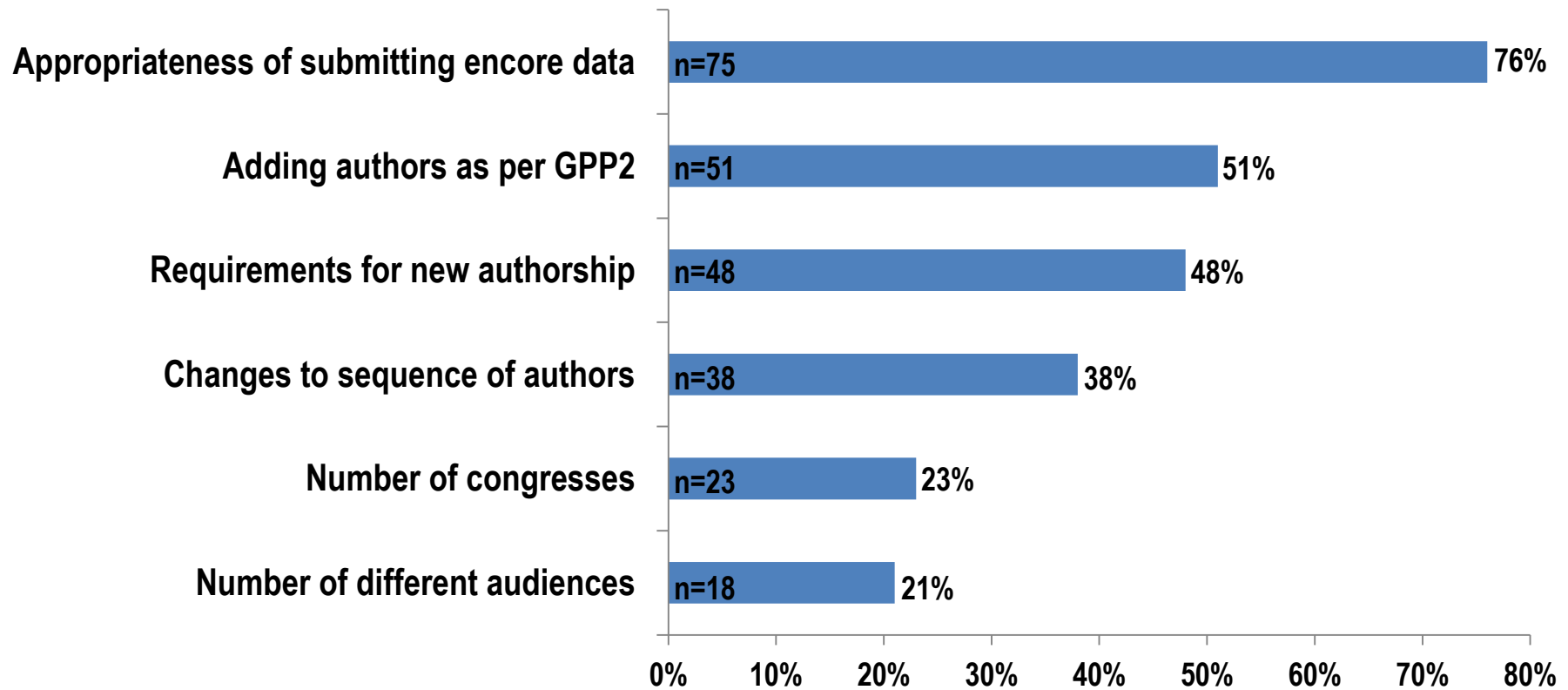
# GUIDANCE ON PRESENTING ENCORE DATA (I)

	Yes	No	Other
<b>Does your current workplace provide any specific guidance on presenting encore data?</b>	<b>35% (67)</b>	<b>28% (53)</b>	<b>37% (70) follow client SOPs, policies and guidance</b>

Answered/Skipped = 190/5

# GUIDANCE ON PRESENTING ENCORE DATA (II)

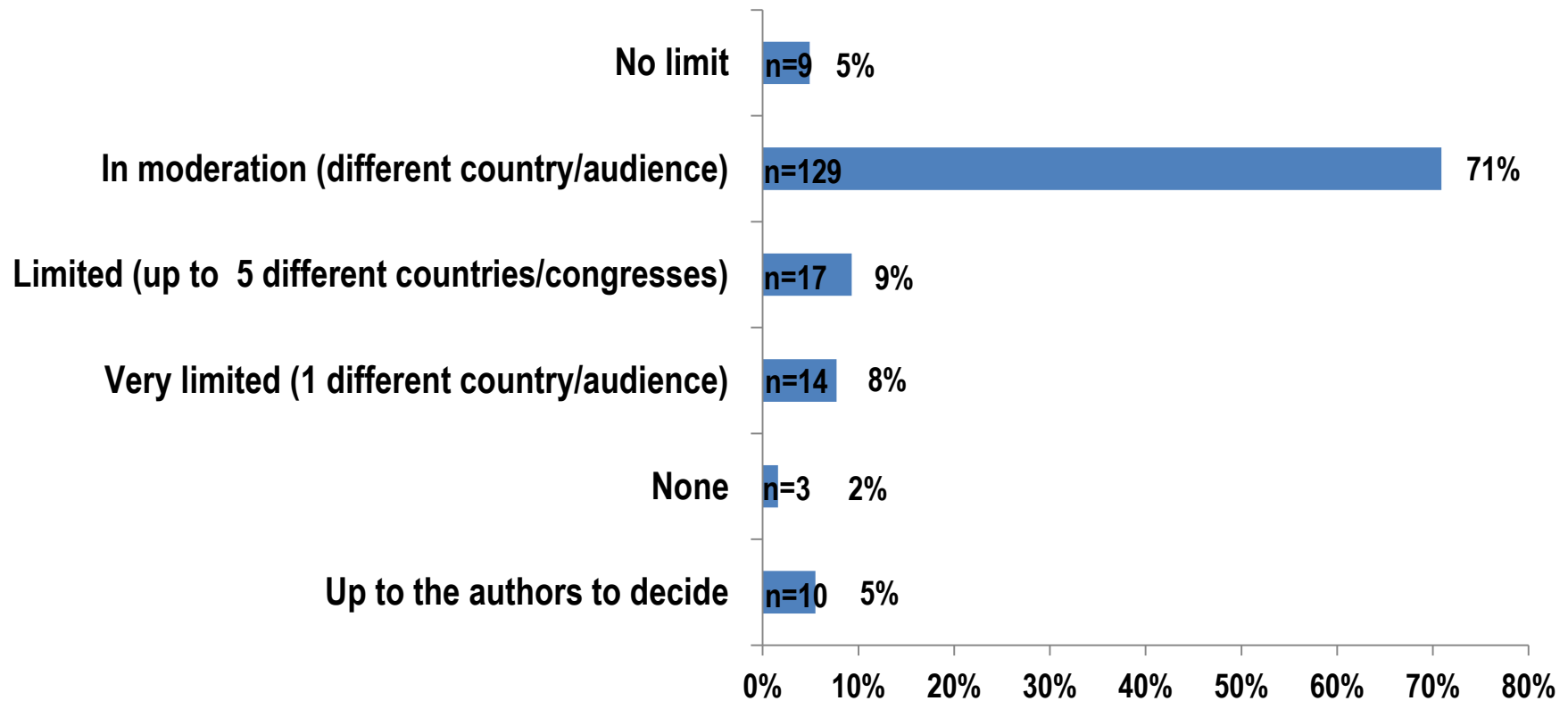
If yes, does the guidance cover the following? (not mutually exclusive)



\*Answered/Skipped = 85/110

# APPROPRIATENESS OF ENCORE ABSTRACTS

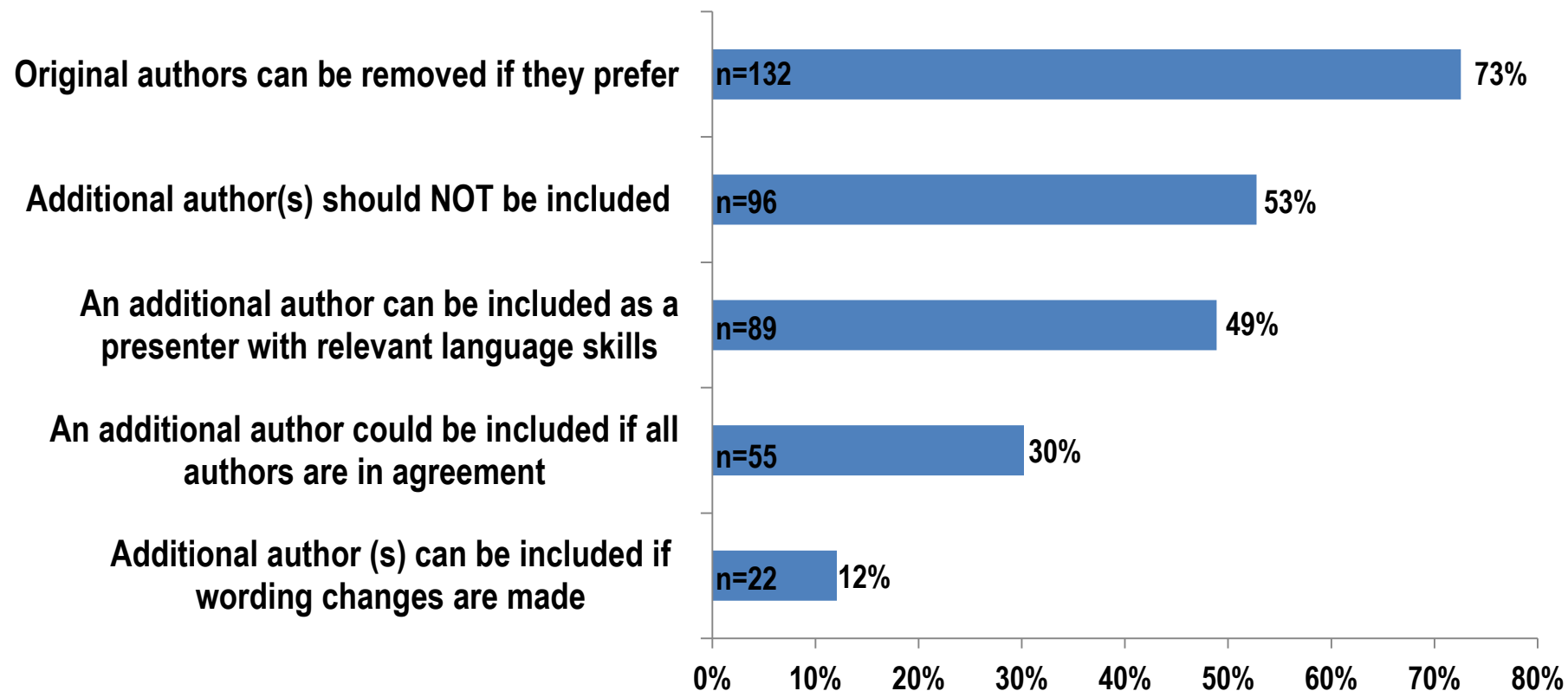
What is the maximum times an abstract should be presented at various congresses?



\*Answered/Skipped = 182/13

# AUTHORSHIP ON ENCORE ABSTRACT SUBMISSIONS

What are your opinions on authorship of encore abstracts? (not mutually exclusive)



\*Answered/Skipped = 182/13

# PRESENTATION OF ENCORE ABSTRACTS

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

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

Answered/Skipped = 182/13

# VALIDATION OF ENCORE ABSTRACT SUBMISSIONS

**What reasons, if any, validate encore data submissions? (not mutually exclusive)**

	Response
Different geography	95% (172)
Different specialty	94% (171)
None/other	3% (5)

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

Answered/Skipped = 182/13



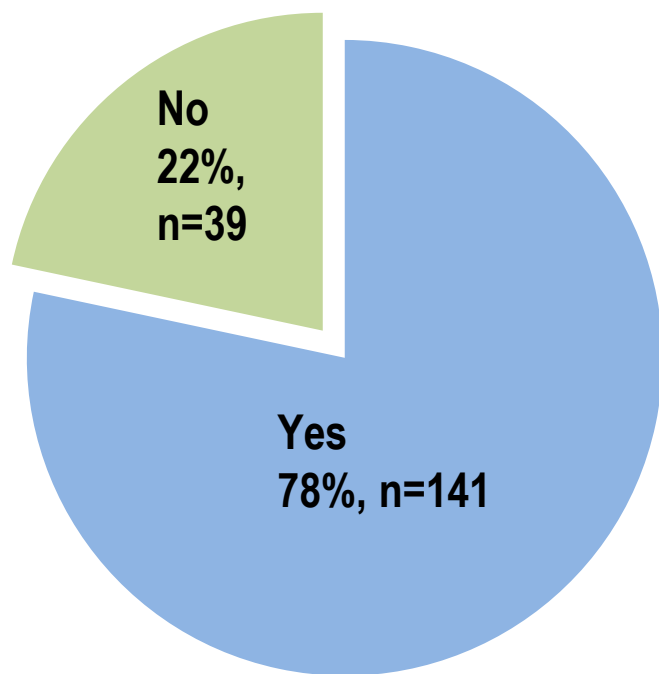
# CONSISTENCY OF ENCORE SUBMISSIONS

	Majority response
<b>Do the same authorship rules apply for a global/international congress that accepts encores vs a local congress?</b>	<b>93% (170) Yes</b>

Answered/Skipped = 182/13

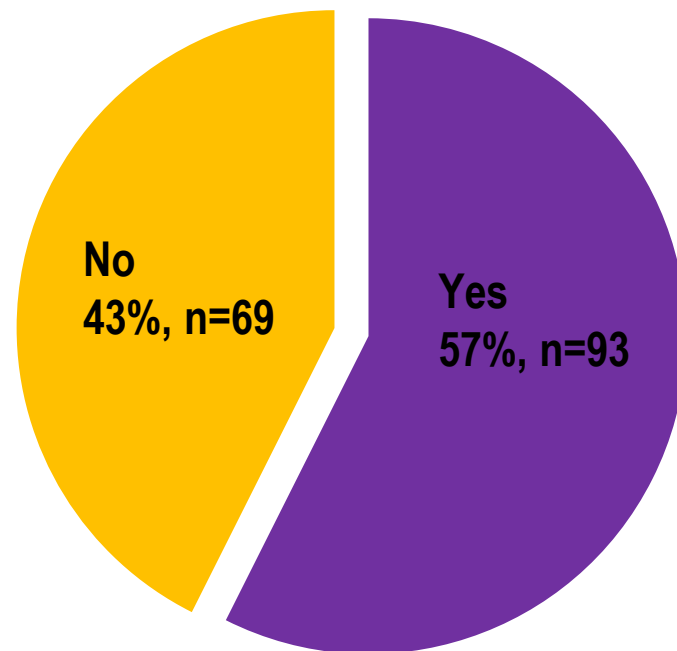
# GUIDANCE AND COPYRIGHT WITH RESPECT TO ENCORE SUBMISSIONS

Should there be more guidance from the publication/medical writing organizations on encore abstracts?



Answered/Skipped = 180/15

Do you consider the original copyright when submitting an encore abstract?



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