

THANK YOU FOR JOINING ISMPP U  
TODAY!

*The program will begin promptly at 11:00 am eastern*

# ISMPP WOULD LIKE TO THANK.....

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The views expressed herein are those of the presenters and they do not necessarily represent the views of their respective employers or of ISMPP

# FACULTY

- Presenters

- Catherine Datto, MD

- Research Physician; AstraZeneca

- Arthur Lazarus, MD, MBA

- Senior Research Physician; AstraZeneca

- Moderator

- Elizabeth Crane

- Senior Manager, Medical Publications, Astellas Pharma Global Development Inc.

The background features a stylized, abstract design with overlapping geometric shapes. A large green shape is on the left, a blue shape with a hexagonal pattern is on the top right, and an orange shape with a hexagonal pattern is on the bottom right. The overall composition is modern and colorful.

# AUTHORS: SETTING EXPECTATIONS AND SUCCESSFUL COLLABORATION

# LEARNING OBJECTIVES

- To describe factors affecting collaboration with authors from both the sponsor's and author's perspectives
- To share results of the ISMPP member survey on current use of authorship agreements
- To discuss successful practices and areas for improvement in collaboration with authors

# INTRODUCTION

- Productive relationships with and among authors
  - Key component of successful management of publications
- Some areas requiring collaboration and agreement
  - Eliciting substantial direction on publication content
  - Establishing mutual understanding of sponsor/academic policies
  - Setting expectations for non-reimbursed time spent on publications
- Authorship agreements can be a key component for setting expectations

# WORKING EFFECTIVELY WITH AUTHORS: SPONSOR 'S PERSPECTIVE

- (Previous) working relationship with company and/or study physicians
- Disease-area experts and publication track record
- Excellent writing/communication skills
- Compliance with timelines
- Confidentiality
- Setting realistic expectations re: time, effort and money
- Cooperation with terms of the contract

The background features a stylized, abstract design. It consists of several overlapping, rounded shapes in shades of green, blue, and orange. A prominent feature is a large, light blue hexagonal pattern that resembles a honeycomb or molecular structure, which is partially obscured by the other shapes. The overall aesthetic is modern and geometric.

# AUTHORSHIP: RESULTS FROM ISMPP MEMBER SURVEY

# COLLABORATION WITH AUTHORS: BACKBONE OF PUBLICATION DEVELOPMENT

- Authors determine the content of publications and decide congresses and journals to which publications will be submitted
- Relationships between sponsors and authors are often long-term throughout lifecycle of a product or therapeutic area
- To successfully collaborate in a complex environment, sponsors and authors must understand each others' perspective and communicate clearly

# AUTHORSHIP AGREEMENTS BACKGROUND

- Limited language pertaining to investigators' ability to publish has been included in study site contracts
- Evolving environment and need to set expectations led GPP2<sup>1</sup> to recommend use of written author agreements
  - Agreement to include, but not limited to:
    - Authors' access to data and ability to publish, accurate and timely publication, no premature or duplicate publications, disclosure of COI and funding sources, authorship/contributorship criteria, decision-making for publication logistics (journal/congress, etc) and both parties share publication policies

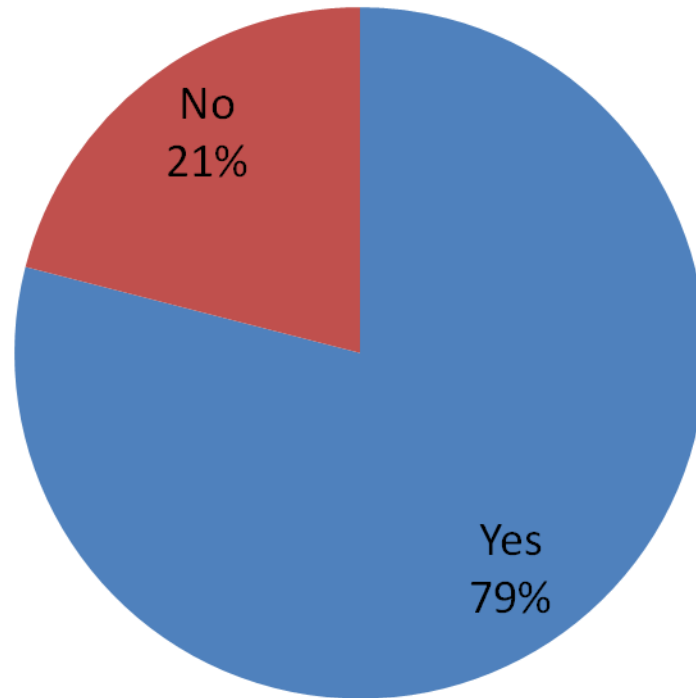
<sup>1</sup><http://www.bmj.com/content/339/bmj.b4330.long>

# BACKGROUND

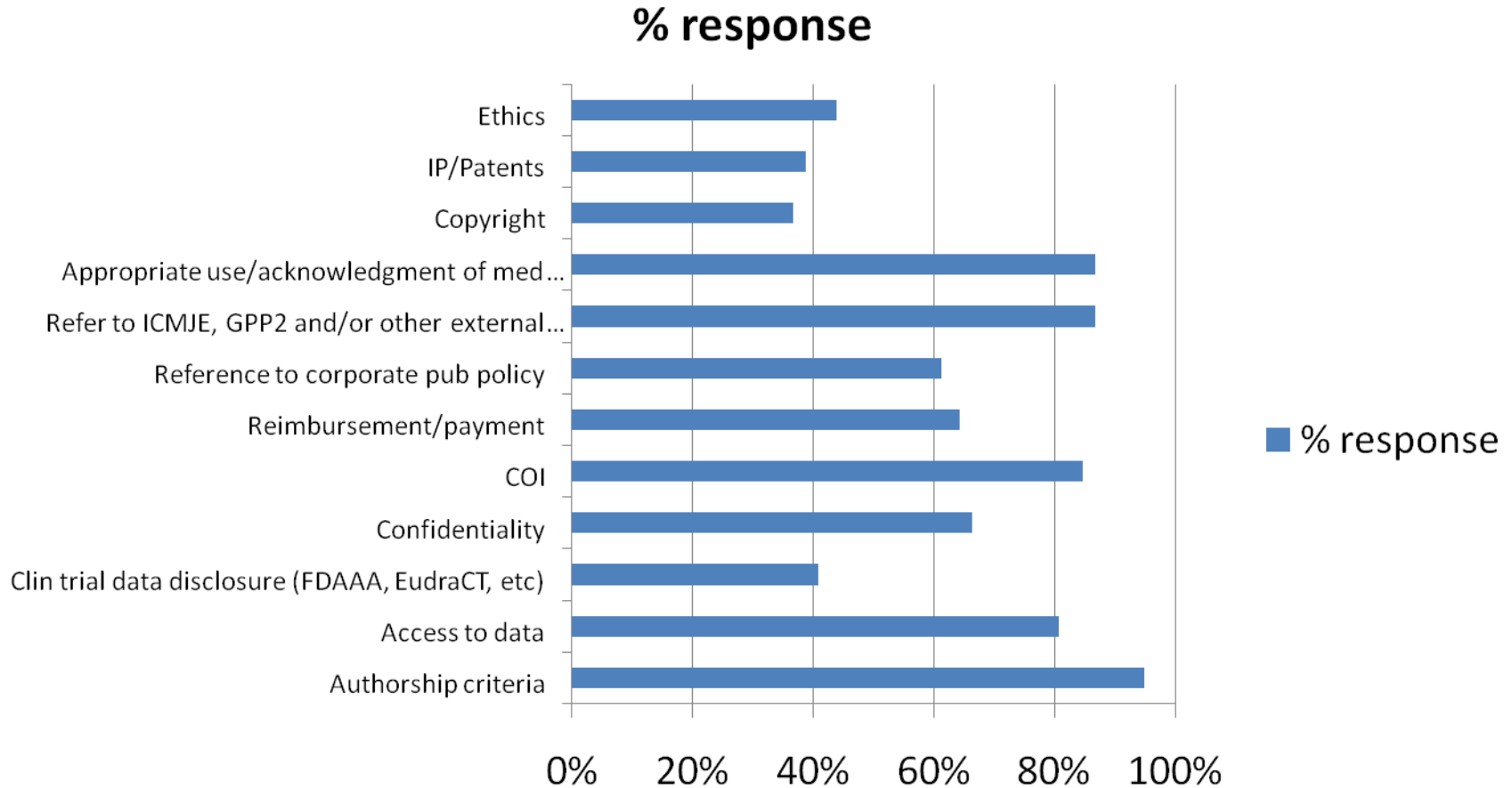
- To support ISMPP U topic and inform current practices surrounding author agreements, an electronic survey was sent to ISMPP membership in 1Q 2011
  - 139 members responded
    - 50% Publication/Communication Agency
    - 38% Pharma or Biotech Company
    - 7% Self-employed
    - 3% Device Company
  - 39% reported that their employer's publication policy requires adherence to GPP2

# DOES YOUR COMPANY UTILIZE (OR HAVE PLANS TO UTILIZE) AUTHORSHIP AGREEMENTS WITH POTENTIAL AUTHORS?

**% response**

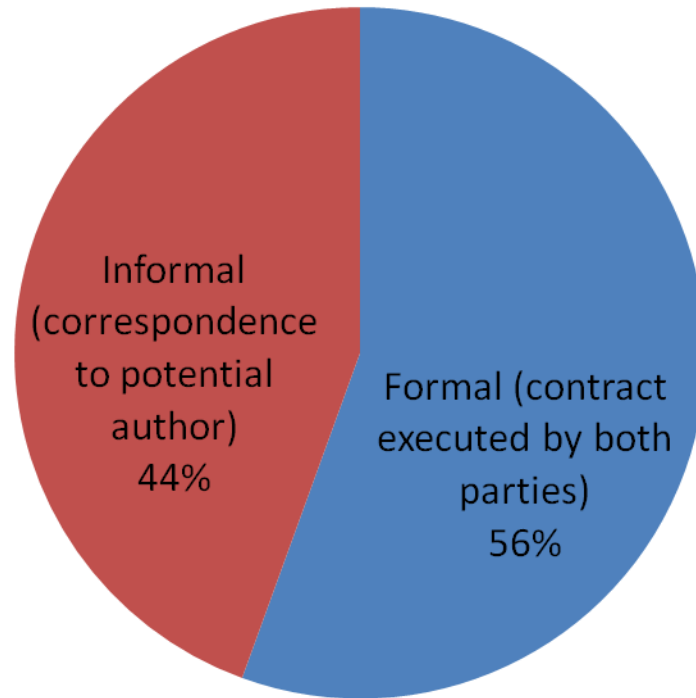


# PLEASE INDICATE WHICH ELEMENTS ARE INCLUDED IN THE AGREEMENTS (CHECK ALL THAT APPLY):



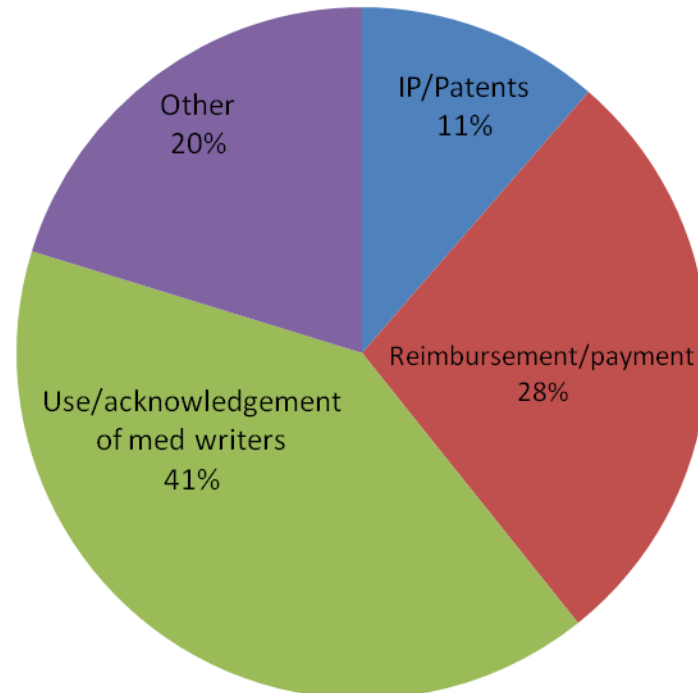
# ARE THE AUTHOR AGREEMENTS BEST DESCRIBED AS:

**% response**



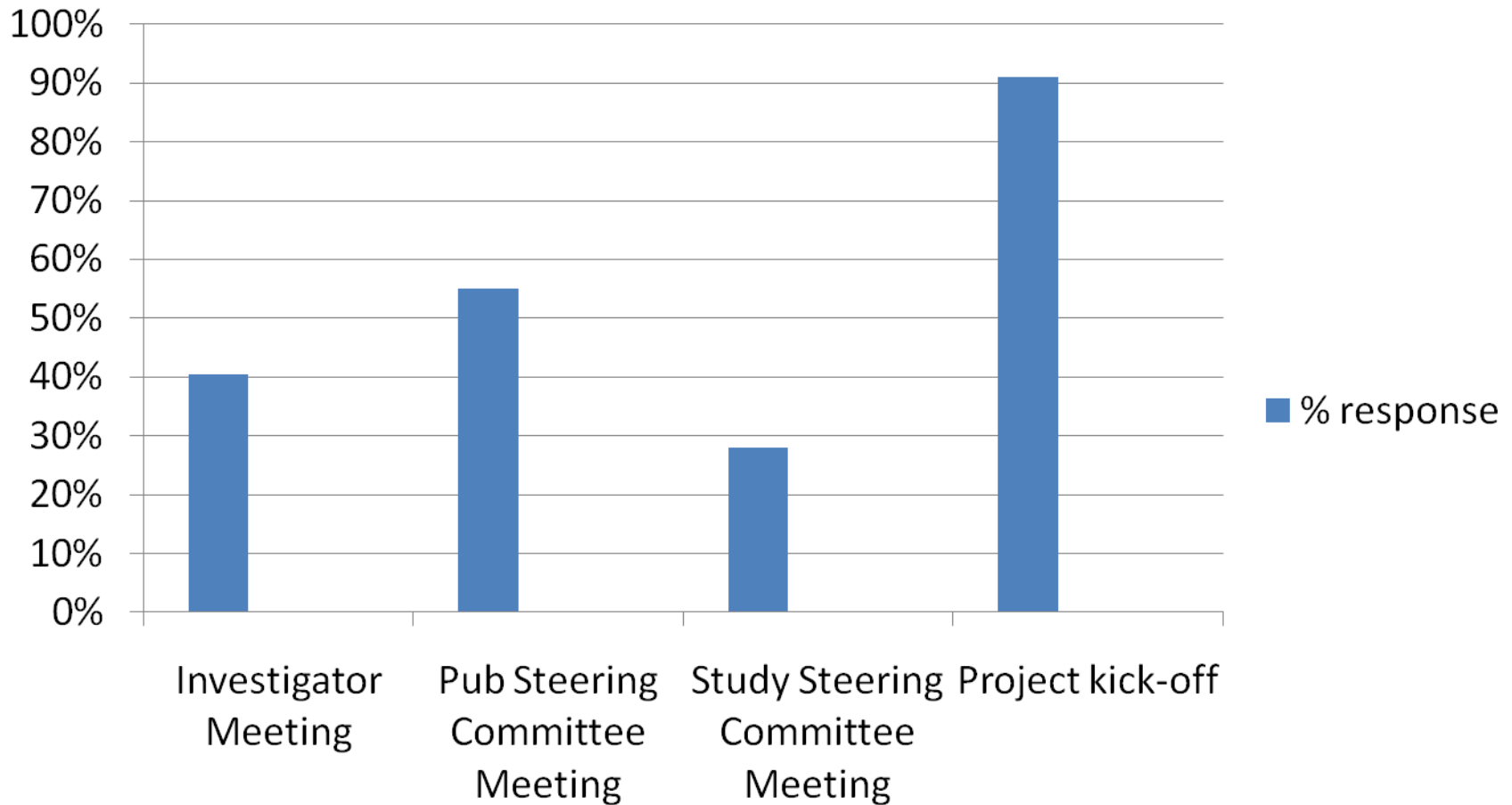
# DO ANY OF YOUR AUTHORS, OR THEIR INSTITUTIONS, HAVE CONCERNS/COMPLAINTS ABOUT AUTHORSHIP AGREEMENTS?

**% response**



Other responses included complaints about paperwork, insurance needs, and newness of agreements precluding certainty about authors' concerns

# IN YOUR COMPANY, AT WHAT OTHER TIME POINTS MAY POTENTIAL AUTHORS BE INFORMED OF, OR TRAINED ON, EXPECTATIONS FOR AUTHORS? (CHECK ALL THAT APPLY)



# WORKING EFFECTIVELY WITH AUTHORS: AUTHOR'S PERSPECTIVE

- (Previous) working relationship with specific individuals within company and/or medical communication team
- Disease-area experts within the sponsor organization
- Interesting topics and novel opportunities
- Reasonable compensation for time and effort on non-publication activities
- Writing assistance
- Reasonable timelines
- Transparency and access to data for analyses

# OPPORTUNITIES FOR IMPROVEMENT

- Engaging junior faculty
- Managing disclosure of conflicts of interest
- Working with diverse authors
- Delineating promotional from scientific
- Relationships between industry, academia, and journal editors

# QUESTIONS.....

To ask a question, please type your query into the 'Q&A' chat box at the bottom left of your screen. Every attempt will be made to answer all questions.

**THANK YOU FOR ATTENDING!**

**We hope you enjoyed today's presentation**

**Please take a moment to fill out the survey sent to you after today's program so you can provide valuable feedback, as it will help us to develop future educational offerings**